Australian Government

Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

General Pharmaceutical Schedule - Volume 1

Effective 1 July 2024

This Schedule is also available at www.pbs.gov.au

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

Fees, Patient Contributions and Safety Net Thresholds **1**
Summary of Changes **2**
About the Schedule **20**
Symbols and Abbreviations Used in the Schedule 20
Restricted Benefits 21
Guidelines and General Statements **22**
General Statement for Drugs for the Treatment of Hepatitis C 22
Pharmaceutical Benefits Schedules **24**
Prescriber Bag 25
General Pharmaceutical Benefits 30
Palliative Care 1621
Repatriation Pharmaceutical Benefits Scheme 1644
Extemporaneously Prepared Benefits **1702**
Drug Tariff 1703
Container Prices 1706
Standard Formula Preparations 1707
Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits 1708
Index of Manufacturers' Code **1709**
Generic/Proprietary Index **1712**

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 July 2024 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$8.67
	Dangerous drug fee	$5.37
	Extemporaneously-prepared	$10.71
	Allowable additional patient charge*	$3.45
Additional Fees (for safety net prices):	Ready-prepared	$1.45
	Extemporaneously-prepared	$1.87
Patient Co-payments:	General	$31.60
	Concessional	$7.70
Safety Net Thresholds:	General	$1647.90
	Concessional	$277.20
Safety Net Card Issue Fee:		$12.04

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 July 2024. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Deletions

Deletion – Brand

13801J *Benzylpenicillin Benzathine (Brancaster Pharma, UK), OJ* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

Alterations

Alteration – Note

11755Q **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes *(Bicillin L-A)*

13801J **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack *(Extencilline Benzathine Benzylpenicillin (France))*

General Pharmaceutical Benefits

Additions

Addition – Item

14188R **MELATONIN**, melatonin 1 mg modified release tablet, 60 *(Slenyto)*

14211Y **MELATONIN**, melatonin 5 mg modified release tablet, 30 *(Slenyto)*

14202L **METHADONE**, methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials *(Physeptone)*

14203M **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(RA-Morph (NZ))*

14220K **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(RA-Morph (NZ))*

14194C **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(RA-Morph (NZ))*

14204N **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(RA-Morph (NZ))*

14172X **NIRAPARIB**, niraparib 100 mg tablet, 56 *(Zejula)*

14173Y **NIRAPARIB**, niraparib 100 mg tablet, 84 *(Zejula)*

14179G **NIRAPARIB**, niraparib 100 mg tablet, 56 *(Zejula)*

14190W **NIRAPARIB**, niraparib 100 mg tablet, 84 *(Zejula)*

14196E **NIRAPARIB**, niraparib 100 mg tablet, 56 *(Zejula)*

14206Q **NIRAPARIB**, niraparib 100 mg tablet, 56 *(Zejula)*

14207R **NIRAPARIB**, niraparib 100 mg tablet, 84 *(Zejula)*

14212B **NIRAPARIB**, niraparib 100 mg tablet, 84 *(Zejula)*

14181J **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

14216F **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

14208T **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

14215E **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

Addition – Brand

1007B	*ARX-ACICLOVIR, XT* – **ACICLOVIR**, aciclovir 200 mg tablet, 90
13532F	*APX-AMLODIPINE, TW* – **AMLODIPINE**, amlodipine 5 mg tablet, 30
2751T	*APX-AMLODIPINE, TW* – **AMLODIPINE**, amlodipine 5 mg tablet, 30
8844L	*BIVALIRUDIN ARX, XT* – **BIVALIRUDIN**, bivalirudin 250 mg injection, 1 vial
10241B	*BTC Desvenlafaxine, BG* – **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28
10231L	*BTC Desvenlafaxine, BG* – **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28
8431R	*SalplusF DPI 250/50, SZ* – **FLUTICASONE PROPIONATE + SALMETEROL**, fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations
8432T	*SalplusF DPI 500/50, SZ* – **FLUTICASONE PROPIONATE + SALMETEROL**, fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations
13848W	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30
8450R	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30
13870B	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30
8451T	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30
14020X	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30
8533D	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30
14055R	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30
8452W	*ARX-GLIMEPIRIDE, XT* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30
13940Q	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30
14068K	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30
5449T	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30
8374R	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30
13998R	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30
14069L	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30
5450W	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30
8375T	*APO-LEFLUNOMIDE, TX* – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30
13411W	*ARX-LERCANIDIPINE, TX* – **LERCANIDIPINE**, lercanidipine hydrochloride 10 mg tablet, 28
8534E	*ARX-LERCANIDIPINE, TX* – **LERCANIDIPINE**, lercanidipine hydrochloride 10 mg tablet, 28
13939P	*ARX-LETROZOLE, XT* – **LETROZOLE**, letrozole 2.5 mg tablet, 30
8245Y	*ARX-LETROZOLE, XT* – **LETROZOLE**, letrozole 2.5 mg tablet, 30
13992K	*Levetiracetam Viatris, MQ* – **LEVETIRACETAM**, levetiracetam 250 mg tablet, 60
8654L	*Levetiracetam Viatris, MQ* – **LEVETIRACETAM**, levetiracetam 250 mg tablet, 60
13937M	*Levetiracetam Viatris, MQ* – **LEVETIRACETAM**, levetiracetam 1 g tablet, 60
8656N	*Levetiracetam Viatris, MQ* – **LEVETIRACETAM**, levetiracetam 1 g tablet, 60
8370M	*ARX-NALTREXONE, XT* – **NALTREXONE**, naltrexone hydrochloride 50 mg tablet, 30
8170B	*APO-OLANZAPINE, TX* – **OLANZAPINE**, olanzapine 2.5 mg tablet, 28
11681T	*APX-PANTOPRAZOLE, TW* – **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30
12277E	*APX-PANTOPRAZOLE, TW* – **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30
8007K	*APX-PANTOPRAZOLE, TW* – **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30
8008L	*APX-PANTOPRAZOLE, TW* – **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30
11406H	*Pirfenidone Dr.Reddy's, RZ* – **PIRFENIDONE**, pirfenidone 267 mg tablet, 90
11410M	*Pirfenidone Dr.Reddy's, RZ* – **PIRFENIDONE**, pirfenidone 801 mg tablet, 90
13588E	*APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30
2574L	*APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

13589F *APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2594M *APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

11856B *ARX-SEVELAMER, XT* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

14027G *ARX-SEVELAMER, XT* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

14021Y *Sitagliptin Mylan, AF* – **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28

9180E *Sitagliptin Mylan, AF* – **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28

14058X *Sitagliptin Mylan, AF* – **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28

9181F *Sitagliptin Mylan, AF* – **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28

13871C *Sitagliptin Mylan, AF* – **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28

9182G *Sitagliptin Mylan, AF* – **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28

13994M *Sitagliptin/Metformin Mylan 50/500, AF* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

9449H *Sitagliptin/Metformin Mylan 50/500, AF* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

14064F *Sitagliptin/Metformin Mylan 50/850, AF* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

9450J *Sitagliptin/Metformin Mylan 50/850, AF* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

14035Q *Sitagliptin/Metformin Mylan 50/1000, AF* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

9451K *Sitagliptin/Metformin Mylan 50/1000, AF* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

5469W *Varenicline Viatris, AF* – **VARENICLINE**, varenicline 1 mg tablet, 56

9129L *Varenicline Viatris, AF* – **VARENICLINE**, varenicline 1 mg tablet, 56

Addition – Equivalence Indicator

8844L *Bivalirudin APOTEX, TX* – **BIVALIRUDIN**, bivalirudin 250 mg injection, 1 vial

13258T *Bufomix Easyhaler 400/12, OX* – **BUDESONIDE + FORMOTEROL**, budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

2123R *Ordine 5, XT* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

5238Q *Ordine 5, XT* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

8370M *Naltrexone GH, GQ* – **NALTREXONE**, naltrexone hydrochloride 50 mg tablet, 30

13079J *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

13089X *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

13092C *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

13112D *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

14088L *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

14094T *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

14098B *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

14104H *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

Addition – Note

2123R **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(Ordine 5)*

5238Q **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(Ordine 5)*

13079J **NIRAPARIB**, niraparib 100 mg capsule, 84 *(Zejula)*

13089X **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

13092C **NIRAPARIB**, niraparib 100 mg capsule, 84 *(Zejula)*

13112D **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

14088L **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

14094T **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

14098B **NIRAPARIB**, niraparib 100 mg capsule, 84 *(Zejula)*

14104H **NIRAPARIB**, niraparib 100 mg capsule, 84 *(Zejula)*

Deletions

Deletion – Item

13694R **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 50 mL *(Amoxicillin and clavulanate potassium for oral suspension, USP 400 mg/57 mg per 5 mL (Aurobindo))*

13728M **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 50 mL *(Amoxicillin and clavulanate potassium for oral suspension, USP 400 mg/57 mg per 5 mL (Aurobindo))*

13179P **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20 *(Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge))*

13190F **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20 *(Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge))*

13194K **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20 *(Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge))*

13282C **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL *(Penopen)*

13291M **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL *(Penopen)*

12670W **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge *(Terrosa)*

13891D **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge *(Terrosa)*

13341E **VARENICLINE**, varenicline 500 microgram tablet, 56 *(APO-Varenicline (Canada))*

Deletion – Brand

8717T *Aripic Aripiprazole, LR* – **ARIPIPRAZOLE**, aripiprazole 10 mg tablet, 30

13495G *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8213G *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

13468W *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

8215J *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

13790T *Benzylpenicillin Benzathine (Brancaster Pharma, UK), OJ* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13816E *Benzylpenicillin Benzathine (Brancaster Pharma, UK), OJ* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13592J *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

8295N *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

13436E *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

8296P *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

13565Y *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

8297Q *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

13438G *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

8889W *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

11169W *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 2 g injection, 5 vials

12112L *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 2 g injection, 10 vials

3138E *Clindamycin BNM, BZ* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

5057E *Clindamycin BNM, BZ* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

9318K *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9322P *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9319L *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

9323Q *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

3118D *Depo-Ralovera, FZ* – **MEDROXYPROGESTERONE**, medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

12001P *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

1760P *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

5260W *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

11993F *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

5261X *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

8016X *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

13969F *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

8163P *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

13913G *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

8164Q *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

14008G *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

8165R *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

14009H *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

8166T *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

Deletion – Equivalence Indicator

9318K *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9322P *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9319L *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

9323Q *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

5029Q *Phenoxymethylpenicillin-AFT, AE* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

8977L *Phenoxymethylpenicillin-AFT, AE* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

Deletion – Note

5011R **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL *(Augmentin Duo 400, Curam Duo)*

8319W **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL *(Augmentin Duo 400, Curam Duo)*

11933C **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10 *(AMCLAVOX DUO FORTE 875/125, APO-AMOXY/CLAV 875/125, APO-Amoxycillin and Clavulanic Acid, APX-Amoxicillin/Clavulanic Acid, AlphaClav Duo Forte, Alphaclav Duo Forte Viatris, AmoxyClav generichealth 875/125, Augmentin Duo forte, Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125, Curam Duo Forte 875/125)*

5006L **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10 *(AMCLAVOX DUO FORTE 875/125, APO-AMOXY/CLAV 875/125, APO-Amoxycillin and Clavulanic Acid, APX-Amoxicillin/Clavulanic Acid, AlphaClav Duo Forte, Alphaclav Duo Forte Viatris, AmoxyClav generichealth 875/125, Augmentin Duo forte, Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125, Curam Duo Forte 875/125)*

8254K **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10 *(AMCLAVOX DUO FORTE 875/125, APO-AMOXY/CLAV 875/125, APO-Amoxycillin and Clavulanic Acid, APX-Amoxicillin/Clavulanic Acid, AlphaClav Duo Forte, Alphaclav Duo Forte Viatris, AmoxyClav generichealth 875/125, Augmentin Duo forte, Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125, Curam Duo Forte 875/125)*

10958R **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

11484K **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

11193D **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

11485L **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

13290L **LENVATINIB**, lenvatinib 4 mg capsule, 30 *(Lenvima)*

13283D **LENVATINIB**, lenvatinib 10 mg capsule, 30 *(Lenvima)*

5029Q **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL *(Phenoxymethylpenicillin-AFT)*

8977L **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL *(Phenoxymethylpenicillin-AFT)*

14093R **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL pen device *(Teriparatide Lupin, Terrosa)*

5469W **VARENICLINE**, varenicline 1 mg tablet, 56 *(Champix, PHARMACOR VARENICLINE, VARENAPIX, Varenicline Viatris)*

9129L **VARENICLINE**, varenicline 1 mg tablet, 56 *(Champix, PHARMACOR VARENICLINE, VARENAPIX, Varenicline Viatris)*

Deletion – Restriction

13290L **LENVATINIB**, lenvatinib 4 mg capsule, 30 *(Lenvima)*

13283D **LENVATINIB**, lenvatinib 10 mg capsule, 30 *(Lenvima)*

Alterations

Alteration – Authorised Prescriber

		From	*To*
13485R	**CALCIUM**, calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120 *(Cal-500)*	M,N	M

Alteration – Note

2267H **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes *(Bicillin L-A)*

5027N **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes *(Bicillin L-A)*

13790T **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack *(Extencilline Benzathine Benzylpenicillin (France))*

13816E **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack *(Extencilline Benzathine Benzylpenicillin (France))*

14077X **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL *(Morphini HCl Streuli)*

14083F **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL *(Morphini HCl Streuli)*

2124T **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(Ordine 10)*

5239R **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(Ordine 10)*

Alteration – Restriction

12613W **ALIROCUMAB**, alirocumab 75 mg/mL injection, 2 x 1 mL pen devices *(Praluent)*

12604J **ALIROCUMAB**, alirocumab 150 mg/mL injection, 2 x 1 mL pen devices *(Praluent)*

13649J **DEUCRAVACITINIB**, deucravacitinib 6 mg tablet, 28 *(Sotyktu)*

10958R **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

11484K **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

11193D **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

11485L **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

14101E **INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*

14152W **INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*

14100D **TAFAMIDIS**, tafamidis 61 mg capsule, 30 *(Vyndamax)*

Alteration – Restriction Level

		From	*To*
10958R	**EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*	authority-required	streamlined

11484K	**EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*	authority-required	streamlined
11193D	**EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*	authority-required	streamlined
11485L	**EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*	authority-required	streamlined

Alteration – Manufacturer Code

		From	*To*
1270W	*Androcur* – **CYPROTERONE**, cyproterone acetate 50 mg tablet, 50	BN	GH
14023C	*Androcur* – **CYPROTERONE**, cyproterone acetate 50 mg tablet, 50	BN	GH
14022B	*Androcur-100* – **CYPROTERONE**, cyproterone acetate 100 mg tablet, 50	BN	GH
8019C	*Androcur-100* – **CYPROTERONE**, cyproterone acetate 100 mg tablet, 50	BN	GH
11753N	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11762C	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11769K	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11775R	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11780B	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11781C	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11784F	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11787J	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11880G	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
5443L	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9111M	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9113P	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9115R	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9123E	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9172R	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9174W	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9176Y	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
9178C	*Glivec* – **IMATINIB**, imatinib 100 mg tablet, 60	AF	NV
11752M	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11758W	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11765F	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11778X	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11785G	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11786H	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11788K	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11789L	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
11878E	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
5444M	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9112N	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9114Q	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9116T	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9124F	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9173T	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV

9175X	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9177B	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
9179D	*Glivec* – **IMATINIB**, imatinib 400 mg tablet, 30	AF	NV
10205D	*Reandron 1000* – **TESTOSTERONE UNDECANOATE**, testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial	BN	AS

Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.

Further information on Supply Only arrangements is available at https://www.pbs.gov.au/browse/medicine-listing/supply-only

12117R **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 *(Calquence)*

12826C **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 *(Calquence)*

1606M **METHADONE**, methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Physeptone)*

Advance Notices

1 August 2024

Deletion – Brand

8357W *Acamprosate Mylan, AL* – **ACAMPROSATE**, acamprosate calcium 333 mg enteric tablet, 180

13955L *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

8188Y *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

12604J *Praluent, SW* – **ALIROCUMAB**, alirocumab 150 mg/mL injection, 2 x 1 mL pen devices

12607M *Praluent, SW* – **ALIROCUMAB**, alirocumab 75 mg/mL injection, 2 x 1 mL pen devices

12608N *Praluent, SW* – **ALIROCUMAB**, alirocumab 150 mg/mL injection, 2 x 1 mL pen devices

12613W *Praluent, SW* – **ALIROCUMAB**, alirocumab 75 mg/mL injection, 2 x 1 mL pen devices

2900P *Alfamino, NT* – **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

2928D *Alfamino, NT* – **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

12115P *Cephazolin Alphapharm, AF* – **CEFAZOLIN**, cefazolin 2 g injection, 10 vials

12118T *Cephazolin Alphapharm, AF* – **CEFAZOLIN**, cefazolin 2 g injection, 10 vials

1256D *Cefazolin-AFT, AE* – **CEFAZOLIN**, cefazolin 500 mg injection, 5 vials

5477G *Cefazolin-AFT, AE* – **CEFAZOLIN**, cefazolin 500 mg injection, 5 vials

1788D *Ceftriaxone Viatris, AL* – **CEFTRIAXONE**, ceftriaxone 1 g injection, 5 vials

9159C *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

13440J *Blooms The Chemist Ezetimibe, IB* – **EZETIMIBE**, ezetimibe 10 mg tablet, 30

8757X *Blooms The Chemist Ezetimibe, IB* – **EZETIMIBE**, ezetimibe 10 mg tablet, 30

1204J *FML Liquifilm, VE* – **FLUOROMETHOLONE**, fluorometholone 0.1% eye drops, 5 mL

5513E *FML Liquifilm, VE* – **FLUOROMETHOLONE**, fluorometholone 0.1% eye drops, 5 mL

1704Q *Leucovorin Calcium (Pfizer Australia Pty Ltd), PF* – **FOLINIC ACID**, folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules

3104J *Diastix, DX* – **GLUCOSE INDICATOR URINE**, glucose indicator urine diagnostic strip, 50

12255B *Mixtard 30/70 InnoLet, NI* – **INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN**, insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL pen devices

1542E *Aeron 250, AL* – **IPRATROPIUM**, ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules

8238N *Aeron 500, AL* – **IPRATROPIUM**, ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules

13847T *Blooms the Chemist Metformin XR 1000, IB* – **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60

13899M *Blooms the Chemist Metformin XR 500, IB* – **METFORMIN**, metformin hydrochloride 500 mg modified release tablet, 120

3439B *Blooms the Chemist Metformin XR 1000, IB* – **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60

9435N *Blooms the Chemist Metformin XR 500, IB* – **METFORMIN**, metformin hydrochloride 500 mg modified release tablet, 120

13884R *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

14000W *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

8649F *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

8650G *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

13079J *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

13089X *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

13092C *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

13112D *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

14088L *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

14094T *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 56

14098B *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

14104H *Zejula, GK* – **NIRAPARIB**, niraparib 100 mg capsule, 84

2961W *Corbeton 40, AF* – **OXPRENOLOL**, oxprenolol hydrochloride 40 mg tablet, 100

2335X *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2348N *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2363J *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2676W *Alfaré, NT* – **PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**, protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g

2748P *Saflutan, MF* – **TAFLUPROST**, tafluprost 0.0015% eye drops, 30 x 0.3 mL ampoules

2755B *Saflutan, MF* – **TAFLUPROST**, tafluprost 0.0015% eye drops, 30 x 0.3 mL ampoules

1 September 2024

Deletion – Brand

11933C *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

5006L *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

10024N *Symbicort Rapihaler 50/3, AP* – **BUDESONIDE + FORMOTEROL**, budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

12100W *Symbicort Rapihaler 50/3, AP* – **BUDESONIDE + FORMOTEROL**, budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

8401E *Fosetic 20/12.5, ZP* – **FOSINOPRIL + HYDROCHLOROTHIAZIDE**, fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

8729K *Granisetron Kabi, PK* – **GRANISETRON**, granisetron 3 mg/3 mL injection, 3 mL ampoule

8730L *Granisetron Kabi, PK* – **GRANISETRON**, granisetron 3 mg/3 mL injection, 3 mL ampoule

1 October 2024

Deletion – Brand

10790X *Dicloxacillin Mylan 500, AL* – **DICLOXACILLIN**, dicloxacillin 500 mg capsule, 24

5097G *Dicloxacillin Mylan 500, AL* – **DICLOXACILLIN**, dicloxacillin 500 mg capsule, 24

8122L *Dicloxacillin Mylan 500, AL* – **DICLOXACILLIN**, dicloxacillin 500 mg capsule, 24

Palliative Care

Additions

Addition – Item

14193B **METHADONE**, methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials *(Physeptone)*

14186P **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(RA-Morph (NZ))*

14187Q **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(RA-Morph (NZ))*

Addition – Equivalence Indicator

12549L *Ordine 5, XT* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

Addition – Note

12549L **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(Ordine 5)*

Alterations

Alteration – Note

12472K **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(Ordine 10)*

14081D **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL *(Morphini HCl Streuli)*

Supply Only

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12481X **METHADONE**, methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Physeptone)*

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

14189T **ANIFROLUMAB**, anifrolumab 300 mg/2 mL injection, 2 mL vial *(Saphnelo)*

14170T **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

14214D **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

14213C **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL vials *(Octreotide Acetate Omega (Canada))*

14177E **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL vials *(Octreotide Acetate Omega (Canada))*

14201K **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL vials *(Octreotide Acetate Omega (Canada))*

Addition – Brand

11838C *ARX-SEVELAMER, XT* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

Addition – Note

6227R **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.05)*

6228T **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.1)*

6229W **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.5)*

Deletions

Deletion – Note

13317X **AVATROMBOPAG**, avatrombopag 20 mg tablet, 30 *(Doptelet)*

Deletion – Restriction

13099K **SELINEXOR**, selinexor 20 mg tablet, 16 *(Xpovio)*

13103P **SELINEXOR**, selinexor 20 mg tablet, 20 *(Xpovio)*

Alterations

Alteration – Note

11996J **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11997K **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11999M **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

12313C **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12316F **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12294C **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12310X **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12043W **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12051G **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12052H **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

11003D **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11014Q **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11829N **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

10110D **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10956P **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11826K **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11840E **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11952C **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11958J **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10122R **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

10968G **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11825J **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11864K **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11932B **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11953D **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

13099K **SELINEXOR**, selinexor 20 mg tablet, 16 *(Xpovio)*

13103P **SELINEXOR**, selinexor 20 mg tablet, 20 *(Xpovio)*

13105R **SELINEXOR**, selinexor 20 mg tablet, 32 *(Xpovio)*

Alteration – Restriction

13317X **AVATROMBOPAG**, avatrombopag 20 mg tablet, 30 *(Doptelet)*

11996J **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11997K **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11999M **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

6232B **CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*

6352H **CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 25)*

6353J **CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 50)*

6354K **CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 100)*

6125J **CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*

12313C **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12316F **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12294C **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12310X **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12043W **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12051G **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12052H **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

11003D **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11014Q **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11829N **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

10110D **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10956P **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11826K **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11840E **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11952C **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11958J **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10122R **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

10968G **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11825J **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11864K **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11932B **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11953D **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

Advance Notices

1 August 2024

Deletion – Brand

12146G *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

11888Q *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

9627Q *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

11003D *Nucala, GK* – **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial

11014Q *Nucala, GK* – **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial

11829N *Nucala, GK* – **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial

6208R *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

6209T *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

6357N *VALGANCICLOVIR HETERO, GG* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

14195D **ANIFROLUMAB**, anifrolumab 300 mg/2 mL injection, 2 mL vial *(Saphnelo)*

14171W **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

14205P **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

14178F **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL vials *(Octreotide Acetate Omega (Canada))*

14219J **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL vials *(Octreotide Acetate Omega (Canada))*

14218H **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL vials *(Octreotide Acetate Omega (Canada))*

Addition – Brand

11855Y *ARX-SEVELAMER, XT* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

Addition – Note

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

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

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

Deletions

Deletion – Note

13313Q **AVATROMBOPAG**, avatrombopag 20 mg tablet, 30 *(Doptelet)*

Deletion – Restriction

13085Q **SELINEXOR**, selinexor 20 mg tablet, 16 *(Xpovio)*

13086R **SELINEXOR**, selinexor 20 mg tablet, 20 *(Xpovio)*

Alterations

Alteration – Note

11994G **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11995H **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

12000N **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

12309W **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12318H **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12293B **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12302L **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12007Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12021Q **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12064Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

10980X **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

10996R **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11839D **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

10118M **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10967F **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11835X **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11846L **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11946R **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11962N **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10109C **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

10973M **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11824H **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11828M **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11945Q **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11950Y **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

13085Q **SELINEXOR**, selinexor 20 mg tablet, 16 *(Xpovio)*

13086R **SELINEXOR**, selinexor 20 mg tablet, 20 *(Xpovio)*

13104Q **SELINEXOR**, selinexor 20 mg tablet, 32 *(Xpovio)*

Alteration – Restriction

13313Q **AVATROMBOPAG**, avatrombopag 20 mg tablet, 30 *(Doptelet)*

11994G **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11995H **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

12000N **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

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

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

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

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

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

12309W **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12318H **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12293B **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12302L **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12007Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12021Q **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12064Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

10980X **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

10996R **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11839D **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

10118M **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10967F **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11835X **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11846L **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11946R **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

11962N **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Xolair)*

10109C **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

10973M **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11824H **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11828M **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11945Q **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

11950Y **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Xolair)*

Advance Notices

1 August 2024

Deletion – Brand

12149K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

11885M *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

5623Y *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

10980X *Nucala, GK* – **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial

10996R *Nucala, GK* – **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial

11839D *Nucala, GK* – **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial

9501C *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

9502D *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

9569P *VALGANCICLOVIR HETERO, GG* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Highly Specialised Drugs Program (Community Access)

Alterations

Alteration – Restriction

13328L	**BUPRENORPHINE**, buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe *(Buvidal Weekly)*
13297W	**BUPRENORPHINE**, buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe *(Buvidal Weekly)*
13296T	**BUPRENORPHINE**, buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe *(Buvidal Weekly)*
13314R	**BUPRENORPHINE**, buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe *(Buvidal Weekly)*
13298X	**BUPRENORPHINE**, buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe *(Buvidal Monthly)*
13309L	**BUPRENORPHINE**, buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe *(Buvidal Monthly)*
13320C	**BUPRENORPHINE**, buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe *(Sublocade)*
13302D	**BUPRENORPHINE**, buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe *(Buvidal Monthly)*
13303E	**BUPRENORPHINE**, buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe *(Buvidal Monthly)*
13327K	**BUPRENORPHINE**, buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe *(Sublocade)*
13310M	**BUPRENORPHINE**, buprenorphine 400 microgram sublingual tablet, 7 *(Subutex)*
13336X	**BUPRENORPHINE**, buprenorphine 2 mg sublingual tablet, 7 *(Subutex)*
13337Y	**BUPRENORPHINE**, buprenorphine 8 mg sublingual tablet, 7 *(Subutex)*
13322E	**BUPRENORPHINE + NALOXONE**, buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28 *(Suboxone Film 2/0.5)*
13321D	**BUPRENORPHINE + NALOXONE**, buprenorphine 8 mg + naloxone 2 mg sublingual film, 28 *(Suboxone Film 8/2)*
13333R	**METHADONE**, methadone hydrochloride 5 mg/mL oral liquid, 1 L *(Aspen Methadone Syrup, Biodone Forte)*
13334T	**METHADONE**, methadone hydrochloride 5 mg/mL oral liquid, 200 mL *(Aspen Methadone Syrup, Biodone Forte)*

Alteration – Number of Repeats

		From	*To*
13328L	**BUPRENORPHINE**, buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe *(Buvidal Weekly)*	2	5
13297W	**BUPRENORPHINE**, buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe *(Buvidal Weekly)*	2	5
13296T	**BUPRENORPHINE**, buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe *(Buvidal Weekly)*	2	5
13314R	**BUPRENORPHINE**, buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe *(Buvidal Weekly)*	2	5
13298X	**BUPRENORPHINE**, buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe *(Buvidal Monthly)*	2	5
13309L	**BUPRENORPHINE**, buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe *(Buvidal Monthly)*	2	5
13320C	**BUPRENORPHINE**, buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe *(Sublocade)*	2	5
13302D	**BUPRENORPHINE**, buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe *(Buvidal Monthly)*	2	5
13303E	**BUPRENORPHINE**, buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe *(Buvidal Monthly)*	2	5
13327K	**BUPRENORPHINE**, buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe *(Sublocade)*	2	5
13310M	**BUPRENORPHINE**, buprenorphine 400 microgram sublingual tablet, 7 *(Subutex)*	2	5
13336X	**BUPRENORPHINE**, buprenorphine 2 mg sublingual tablet, 7 *(Subutex)*	2	5
13337Y	**BUPRENORPHINE**, buprenorphine 8 mg sublingual tablet, 7 *(Subutex)*	2	5

13322E	**BUPRENORPHINE + NALOXONE**, buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28 *(Suboxone Film 2/0.5)*	2	5
13321D	**BUPRENORPHINE + NALOXONE**, buprenorphine 8 mg + naloxone 2 mg sublingual film, 28 *(Suboxone Film 8/2)*	2	5
13333R	**METHADONE**, methadone hydrochloride 5 mg/mL oral liquid, 1 L *(Aspen Methadone Syrup, Biodone Forte)*	2	5
13334T	**METHADONE**, methadone hydrochloride 5 mg/mL oral liquid, 200 mL *(Aspen Methadone Syrup, Biodone Forte)*	2	5

Advance Notices

1 August 2024

Deletion – Brand

10306K *VALGANCICLOVIR HETERO, GG* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

1 October 2024

Deletion – Brand

10279B *Entecavir Mylan, AF* – **ENTECAVIR**, entecavir 500 microgram tablet, 30

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

14183L **ALFUZOSIN**, alfuzosin hydrochloride 10 mg modified release tablet, 30 *(Xatral SR)*

14176D **CALCIUM**, calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120 *(Cal-500)*

14217G **CALCIUM**, calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120 *(Cal-500)*

14174B **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120 *(CAL-600, Cal-care 600 mg)*

14175C **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120 *(CAL-600, Cal-care 600 mg)*

14180H **CHLORAMPHENICOL**, chloramphenicol 0.5% eye drops, 10 mL *(Chlorsig)*

14210X **DUTASTERIDE**, dutasteride 500 microgram capsule, 30 *(APO-Dutasteride, Avodart)*

14184M **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30 *(Duodart 500ug/400ug)*

14191X **FINASTERIDE**, finasteride 5 mg tablet, 28 *(Finpro)*

14199H **FINASTERIDE**, finasteride 5 mg tablet, 30 *(APO-Finasteride, Finasta, Finasteride GH 5, Finasteride Mylan 5, Finasteride-GA 5, Finide, Finnacar, Pharmacor Finasteride 5, Proscar)*

14209W **RISEDRONATE**, risedronate sodium 5 mg tablet, 28 *(Actonel)*

14197F **RISEDRONATE**, risedronate sodium 35 mg tablet, 4 *(APO-Risedronate, Risedronate Sandoz, Risedronate-GA)*

14198G **RISEDRONATE**, risedronate sodium 35 mg enteric tablet, 4 *(Actonel EC)*

14185N **SILODOSIN**, silodosin 4 mg capsule, 30 *(Urorec)*

14192Y **SILODOSIN**, silodosin 8 mg capsule, 30 *(Urorec)*

14200J **TAMSULOSIN**, tamsulosin hydrochloride 400 microgram modified release tablet, 30 *(Apo-Tamsulosin SR, BTC Tamsulosin SR, Blooms the Chemist Tamsulosin SR, Flomaxtra, Flosix, Tamsulosin Sandoz SR)*

14182K **THIAMINE**, thiamine hydrochloride 100 mg tablet, 100 *(Betavit)*

Addition – Brand

4222F *Fluorouracil Viatris, AF* – **FLUOROURACIL**, fluorouracil 5% cream, 20 g

4279F *HYOSCINE BUTYLBROMIDE-AFT, AE* – **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

4348W *SUPIROCIN, JM* – **MUPIROCIN**, mupirocin 2% cream, 15 g

10598T *Parapane OSTEO, AF* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

10598T *Pharmacy Action OSTEO Relief 665, HQ* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

4070F *BTC Tamsulosin SR, BG* – **TAMSULOSIN**, tamsulosin hydrochloride 400 microgram modified release tablet, 30

Addition – Equivalence Indicator

4348W *Bactroban, GK* – **MUPIROCIN**, mupirocin 2% cream, 15 g

About the Schedule

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

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

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

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

The Repatriation Schedule of Pharmaceutical Benefits provides information about pharmaceutical benefits available under the Repatriation Pharmaceutical Benefits Scheme (RPBS). These may only be prescribed to Department of Veterans' Affairs (DVA) beneficiaries holding a valid repatriation health card. Queries relating to the RPBS can be made to the DVA or go to www.dva.gov.au

Symbols and Abbreviations Used in the Schedule

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

Restricted Benefits

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

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

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

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

Guidelines and General Statements

General Statement for Drugs for the Treatment of Hepatitis C

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

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

Treatment criteria:

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

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

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

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

- evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and
- where possible, evidence of the hepatitis C virus genotype

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

HEPATITIS C - NON-CIRRHOTIC PATIENTS

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

HEPATITIS C – CIRRHOTIC PATIENTS

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

1. SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.
2. GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] for non-cirrhotic patients:
    - treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
    - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
    - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
    - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.
3. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.
4. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.
5. GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:
    - treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
    - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
    - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
    - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

Pharmaceutical Benefits Schedules

Prescriber Bag

▪ ADRENALINE (EPINEPHRINE)

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3451P NP	1	21.10	Link Medical Products Pty Ltd [LM]

▪ ATROPINE SULFATE

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

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3453R NP	1	25.13	Atropine Injection (Pfizer) [WZ]

▪ BENZATHINE BENZYLPENICILLIN

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
13801J NP	10	*511.97	[a] Extencilline Benzathine Benzylpenicillin (France) [YO]

OR

benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
11755Q NP	1	335.98	[a] Bicillin L-A [PF]

▪ BENZATROPINE

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
11265X NP	1	118.61	Benzatropine Injection [FF]

▪ BENZYLPENICILLIN

benzylpenicillin 600 mg injection, 1 vial

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3486L NP	5	*43.17	BenPen [CS]

▪ BENZYLPENICILLIN

benzylpenicillin 3 g injection, 1 vial

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3487M NP	1	23.04	BenPen [CS]

▪ CHLORPROMAZINE

chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3455W NP	1	34.45	Largactil [IX]

OR

▪ HALOPERIDOL

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3456X NP	1	24.66	Serenace [AS]

▪ CLONAZEPAM

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3478C NP	‡1	17.22	Rivotril [PB]

▪ DIPHTHERIA + TETANUS VACCINE

diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3463G NP	2	*137.31	ADT Booster [CS]

▪ FUROSEMIDE

furosemide 20 mg/2 mL injection, 5 x 2 mL ampoules

3466K NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
1	16.58	Lasix [SW]

▪ FUROSEMIDE

furosemide 20 mg tablet, 50

12222G NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	16.15	[a] Frusemix-M [TY]	[a] UREMIDE 20 [AF]

▪ GLUCAGON HYDROCHLORIDE

glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

3467L NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
1	51.10	GlucaGen Hypokit [NO]

▪ GLYCERYL TRINITRATE

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

3475X NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	25.38	Nitrolingual Pumpspray [SW]

▪ HYDROCORTISONE SODIUM SUCCINATE

hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

3470P NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
2	*23.27	Solu-Cortef [PF]

OR

hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

3471Q NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
1	22.22	Solu-Cortef [PF]

▪ HYOSCINE BUTYLBROMIDE

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

3473T NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	20.52	[a] Buscopan [VZ]	[a] HYOSCINE BUTYLBROMIDE-AFT [AE]
		[a] HYOSCINE BUTYLBROMIDE MEDSURGE [DZ]	[a] HYOSCINE BUTYLBROMIDE SXP [XN]

▪ LIDOCAINE

lidocaine hydrochloride monohydrate 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules

10209H NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
1	40.99	Lignocaine Injection (Pfizer) [WZ]

▪ METHOXYFLURANE

methoxyflurane 99.9% (999 mg/g) inhalation solution, 3 mL bottle

3489P

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
1	54.44	Penthrox [DV]

▪ METOCLOPRAMIDE

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

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3476Y NP	1	21.09	METOCLOPRAMIDE INJECTION BP [WZ]

OR

▪ PROCHLORPERAZINE

prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3477B NP	1	23.78	Stemetil [SW]

▪ MIDAZOLAM

midazolam 5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10178Q NP	1	41.23	Pfizer Australia Pty Ltd [PF]

▪ MOLNUPIRAVIR

molnupiravir 200 mg capsule, 40

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
13144T NP	2	*2192.75	Lagevrio [MK]

▪ MORPHINE

morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3479D NP	1	26.55	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

OR

morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3480E NP	1	28.65	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

OR

morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10862Q NP	1	23.58	Morphine Juno [JU]

OR

morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10868B NP	1	26.11	Morphine Juno [JU]

▪ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
10786Q NP	2	*57.69	[a] Naloxone Hydrochloride (DBL) [PF] [a] NALOXONE SXP [XN]	[a] Naloxone Juno [JU]

OR

naloxone hydrochloride 400 microgram/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
11233F NP	1	57.67	NARCAN [FF]

▪ NIRMATRELVIR (&) RITONAVIR

nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
13147Y NP	2	*2216.75	Paxlovid [PF]

▪ PHYTOMENADIONE

phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules

10213M

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
1	26.28	Konakion MM [PB]

▪ PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

3488N

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
2	*36.65	DBL Promethazine Hydrochloride [PF]

▪ SALBUTAMOL

salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

3497C

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	18.83	Salbutamol Cipla [LR]

OR

salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11088N

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	18.47	Ventolin Nebules [GK]

▪ SALBUTAMOL

salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

3496B

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	18.77	Salbutamol Cipla [LR]

OR

salbutamol 100 microgram/actuation inhalation, 200 actuations

12108G

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	19.29	[a] Zempreon CFC-Free with dose counter [AL]
	19.75	[a] Asmol CFC-Free with dose counter [AF]
	21.75	[a] Ventolin CFC-Free with dose counter [GK]

OR

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

11125M

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	18.34	Ventolin Nebules [GK]

OR

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

13828T

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	32.61	pms-SALBUTAMOL [DZ]

▪ TRAMADOL

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

3484J

NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	17.02	[a] Tramadol AN [JU]	[a] Tramadol Sandoz [SZ]
		[a] Tramal 100 [CS]	

General Pharmaceutical Benefits

ALIMENTARY TRACT AND METABOLISM 36

STOMATOLOGICAL PREPARATIONS 36
STOMATOLOGICAL PREPARATIONS 36
DRUGS FOR ACID RELATED DISORDERS 36
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) 36
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS 50
BELLADONNA AND DERIVATIVES, PLAIN 50
PROPULSIVES 50
ANTIEMETICS AND ANTINAUSEANTS 51
ANTIEMETICS AND ANTINAUSEANTS 51
BILE AND LIVER THERAPY 57
BILE THERAPY 57
DRUGS FOR CONSTIPATION 58
DRUGS FOR CONSTIPATION 58
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS 61
INTESTINAL ANTIINFECTIVES 61
ELECTROLYTES WITH CARBOHYDRATES 62
ANTIPROPULSIVES 62
INTESTINAL ANTIINFLAMMATORY AGENTS 63
DIGESTIVES, INCL. ENZYMES 70
DIGESTIVES, INCL. ENZYMES 70
DRUGS USED IN DIABETES 71
INSULINS AND ANALOGUES 71
BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS 74
VITAMINS 102
VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO 102
VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12 103
MINERAL SUPPLEMENTS 104
CALCIUM 104
POTASSIUM 104
OTHER MINERAL SUPPLEMENTS 105
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS 105
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS 105

BLOOD AND BLOOD FORMING ORGANS 110

ANTITHROMBOTIC AGENTS 110

ANTITHROMBOTIC AGENTS ... 110
ANTIHEMORRHAGICS ... 125
ANTIFIBRINOLYTICS ... 125
ANTIANEMIC PREPARATIONS ... 126
IRON PREPARATIONS ... 126
VITAMIN B12 AND FOLIC ACID ... 127
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS ... 128
BLOOD AND RELATED PRODUCTS ... 128
OTHER HEMATOLOGICAL AGENTS ... 128
OTHER HEMATOLOGICAL AGENTS ... 128

CARDIOVASCULAR SYSTEM ... 130

CARDIAC THERAPY ... 130
CARDIAC GLYCOSIDES ... 130
ANTIARRHYTHMICS, CLASS I AND III ... 130
CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES ... 131
VASODILATORS USED IN CARDIAC DISEASES ... 132
OTHER CARDIAC PREPARATIONS ... 136
ANTIHYPERTENSIVES ... 140
ANTIADRENERGIC AGENTS, CENTRALLY ACTING ... 140
ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING ... 142
ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON ... 143
DIURETICS ... 143
LOW-CEILING DIURETICS, THIAZIDES ... 143
LOW-CEILING DIURETICS, EXCL. THIAZIDES ... 144
HIGH-CEILING DIURETICS ... 144
ALDOSTERONE ANTAGONISTS AND OTHER POTASSIUM-SPARING AGENTS ... 145
DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION ... 147
OTHER DIURETICS ... 147
PERIPHERAL VASODILATORS ... 148
PERIPHERAL VASODILATORS ... 148
BETA BLOCKING AGENTS ... 149
BETA BLOCKING AGENTS ... 149
CALCIUM CHANNEL BLOCKERS ... 155
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS ... 155
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS ... 157
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM ... 158
ACE INHIBITORS, PLAIN ... 158
ACE INHIBITORS, COMBINATIONS ... 164
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN ... 169
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS ... 174
LIPID MODIFYING AGENTS ... 186
LIPID MODIFYING AGENTS, PLAIN ... 186
LIPID MODIFYING AGENTS, COMBINATIONS ... 208

DERMATOLOGICALS ... 219

ANTIFUNGALS FOR DERMATOLOGICAL USE ... 219
ANTIFUNGALS FOR TOPICAL USE ... 219
ANTIFUNGALS FOR SYSTEMIC USE ... 220

ANTIPSORIATICS ... 220
ANTIPSORIATICS FOR TOPICAL USE ... 220
ANTIPSORIATICS FOR SYSTEMIC USE ... 221
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE ... 221
CHEMOTHERAPEUTICS FOR TOPICAL USE ... 221
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS ... 222
CORTICOSTEROIDS, PLAIN ... 222
ANTI-ACNE PREPARATIONS ... 231
ANTI-ACNE PREPARATIONS FOR TOPICAL USE ... 231
ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE ... 232
OTHER DERMATOLOGICAL PREPARATIONS ... 233
OTHER DERMATOLOGICAL PREPARATIONS ... 233

GENITO URINARY SYSTEM AND SEX HORMONES ... 236

OTHER GYNECOLOGICALS ... 236
CONTRACEPTIVES FOR TOPICAL USE ... 236
OTHER GYNECOLOGICALS ... 236
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM ... 239
HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE ... 239
ANDROGENS ... 241
ESTROGENS ... 245
PROGESTOGENS ... 247
PROGESTOGENS AND ESTROGENS IN COMBINATION ... 249
GONADOTROPINS AND OTHER OVULATION STIMULANTS ... 250
ANTIANDROGENS ... 253
OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM ... 254
UROLOGICALS ... 254
UROLOGICALS ... 254
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY ... 255

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS ... 257

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES ... 257
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES ... 257
POSTERIOR PITUITARY LOBE HORMONES ... 257
HYPOTHALAMIC HORMONES ... 260
CORTICOSTEROIDS FOR SYSTEMIC USE ... 260
CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN ... 260
THYROID THERAPY ... 266
THYROID PREPARATIONS ... 266
ANTITHYROID PREPARATIONS ... 269
PANCREATIC HORMONES ... 270
GLYCOGENOLYTIC HORMONES ... 270
CALCIUM HOMEOSTASIS ... 270
PARATHYROID HORMONES AND ANALOGUES ... 270
ANTI-PARATHYROID AGENTS ... 271

ANTIINFECTIVES FOR SYSTEMIC USE ... 272

ANTIBACTERIALS FOR SYSTEMIC USE ... 272
TETRACYCLINES ... 272
BETA-LACTAM ANTIBACTERIALS, PENICILLINS ... 274
OTHER BETA-LACTAM ANTIBACTERIALS ... 282

SULFONAMIDES AND TRIMETHOPRIM 287
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS 288
AMINOGLYCOSIDE ANTIBACTERIALS 290
QUINOLONE ANTIBACTERIALS 292
OTHER ANTIBACTERIALS 294
ANTIMYCOTICS FOR SYSTEMIC USE 296
ANTIMYCOTICS FOR SYSTEMIC USE 296
ANTIMYCOBACTERIALS 301
DRUGS FOR TREATMENT OF TUBERCULOSIS 301
DRUGS FOR TREATMENT OF LEPRA 301
ANTIVIRALS FOR SYSTEMIC USE 302
DIRECT ACTING ANTIVIRALS 302
VACCINES 313
BACTERIAL VACCINES 313

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 313

ANTINEOPLASTIC AGENTS 313
ALKYLATING AGENTS 313
ANTIMETABOLITES 315
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS 320
PROTEIN KINASE INHIBITORS 321
MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES 428
OTHER ANTINEOPLASTIC AGENTS 432
ENDOCRINE THERAPY 451
HORMONES AND RELATED AGENTS 451
HORMONE ANTAGONISTS AND RELATED AGENTS 455
IMMUNOSTIMULANTS 465
IMMUNOSTIMULANTS 465
IMMUNOSUPPRESSANTS 467
IMMUNOSUPPRESSANTS 467

MUSCULO-SKELETAL SYSTEM 1353

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS 1353
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS 1353
SPECIFIC ANTIRHEUMATIC AGENTS 1359
MUSCLE RELAXANTS 1360
MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS 1360
MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS 1360
ANTIGOUT PREPARATIONS 1360
ANTIGOUT PREPARATIONS 1360
DRUGS FOR TREATMENT OF BONE DISEASES 1362
DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION 1362

NERVOUS SYSTEM 1375

ANALGESICS 1375
OPIOIDS 1375
OTHER ANALGESICS AND ANTIPYRETICS 1424
ANTIMIGRAINE PREPARATIONS 1426
ANTIEPILEPTICS 1431
ANTIEPILEPTICS 1431

ANTI-PARKINSON DRUGS ... 1457
ANTICHOLINERGIC AGENTS ... 1457
DOPAMINERGIC AGENTS ... 1458
PSYCHOLEPTICS ... 1465
ANTIPSYCHOTICS ... 1465
ANXIOLYTICS ... 1482
HYPNOTICS AND SEDATIVES ... 1484
PSYCHOANALEPTICS ... 1486
ANTIDEPRESSANTS ... 1486
PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS ... 1495
ANTI-DEMENTIA DRUGS ... 1502
OTHER NERVOUS SYSTEM DRUGS ... 1508
PARASYMPATHOMIMETICS ... 1508
DRUGS USED IN ADDICTIVE DISORDERS ... 1508
OTHER NERVOUS SYSTEM DRUGS ... 1511

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS ... 1514

ANTIPROTOZOALS ... 1514
AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES ... 1514
ANTIMALARIALS ... 1514
ANTHELMINTICS ... 1515
ANTITREMATODALS ... 1515
ANTINEMATODAL AGENTS ... 1515
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS ... 1516
ECTOPARASITICIDES, INCL. SCABICIDES ... 1516

RESPIRATORY SYSTEM ... 1517

NASAL PREPARATIONS ... 1517
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE ... 1517
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES ... 1517
ADRENERGICS, INHALANTS ... 1517
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS ... 1533
ADRENERGICS FOR SYSTEMIC USE ... 1537
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES ... 1538
ANTIHISTAMINES FOR SYSTEMIC USE ... 1540
ANTIHISTAMINES FOR SYSTEMIC USE ... 1540

SENSORY ORGANS ... 1540

OPHTHALMOLOGICALS ... 1540
ANTIINFECTIVES ... 1540
ANTIINFLAMMATORY AGENTS ... 1542
ANTIGLAUCOMA PREPARATIONS AND MIOTICS ... 1546
MYDRIATICS AND CYCLOPLEGICS ... 1552
OCULAR VASCULAR DISORDER AGENTS ... 1552
OTHER OPHTHALMOLOGICALS ... 1566
OTOLOGICALS ... 1574
ANTIINFECTIVES ... 1574

CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION 1574
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS 1575
ANTIINFECTIVES 1575

VARIOUS 1575

ALLERGENS 1575
ALLERGENS 1575
ALL OTHER THERAPEUTIC PRODUCTS 1576
ALL OTHER THERAPEUTIC PRODUCTS 1576
DIAGNOSTIC AGENTS 1582
URINE TESTS 1582
GENERAL NUTRIENTS 1582
OTHER NUTRIENTS 1582

General

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN B

amphotericin B 10 mg lozenge, 20

2931G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	17.83	19.28	Fungilin [AS]

NP

amphotericin B 10 mg lozenge, 20

3306B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	17.83	19.28	Fungilin [AS]

DP

Other agents for local oral treatment

BENZYDAMINE

Restricted benefit

Mucositis

Clinical criteria:

- The condition must be radiation induced.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

1121B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	22.17	23.62	Difflam [IL]

NP

BENZYDAMINE

Restricted benefit

Mucositis

Clinical criteria:

- The condition must be radiation induced.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

5032W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	22.17	23.62	Difflam [IL]

DP

DRUGS FOR ACID RELATED DISORDERS

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

H2-receptor antagonists

FAMOTIDINE

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

famotidine 20 mg tablet, 60

2487X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.45	18.90	Ausfam 20 [RW]

NP

famotidine 40 mg tablet, 30

2488Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.45	18.90	Ausfam 40 [RW]

NP

NIZATIDINE

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

nizatidine 150 mg capsule, 60

1505F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.90	25.35	[a] Nizac [RF]	[a] Tacidine [AF]
		[B]7.59	31.49	25.35	[a] Tazac [RW]	

NP

nizatidine 300 mg capsule, 30

1504E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.90	25.35	[a] Nizac [RF]	[a] Tacidine [AF]
		[B]7.59	31.49	25.35	[a] Tazac [RW]	

NP

▪ RANITIDINE

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

ranitidine 150 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1978D NP MW	1	5	..	17.37	18.82	APO-Ranitidine [TX]

ranitidine 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1977C NP	1	5	..	17.37	18.82	APO-Ranitidine [TX]

Proton pump inhibitors

▪ ESOMEPRAZOLE

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

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

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

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

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

Authority required

Gastro-oesophageal reflux disease

Clinical criteria:

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

esomeprazole 40 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8601Q NP	1	1	..	20.76	22.21	[a] APO-Esomeprazole [TY] [a] Esomeprazole GxP [AF] [a] Esomeprazole RBX [RA] [a] Esopreze [BG] [a] Nexole [RF]	[a] Esomeprazole GH [GQ] [a] Esomeprazole Mylan [AL] [a] Esomeprazole Viatris [MQ] [a] Nexazole [RW] [a] NOUMED ESOMEPRAZOLE [VO]
			[B]7.00	27.76	22.21	[a] Nexium [AP]	

esomeprazole 40 mg enteric capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10330Q NP	1	1	..	20.76	22.21	[a] Noxicid Caps [AL]

▪ ESOMEPRAZOLE

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

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

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

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

Clinical criteria:

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

Authority required

Scleroderma oesophagus

Clinical criteria:

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

esomeprazole 40 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3401B NP	1	5	..	20.76	22.21	[a] APO-Esomeprazole [TY] [a] Esomeprazole GxP [AF] [a] Esomeprazole RBX [RA] [a] Esopreze [BG] [a] Nexole [RF]	[a] Esomeprazole GH [GQ] [a] Esomeprazole Mylan [AL] [a] Esomeprazole Viatris [MQ] [a] Nexazole [RW] [a] NOUMED ESOMEPRAZOLE [VO]
			[B]7.00	27.76	22.21	[a] Nexium [AP]	

esomeprazole 40 mg enteric capsule, 30

10331R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	20.76	22.21	[a] Noxicid Caps [AL]

▪ ESOMEPRAZOLE

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

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

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

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

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

Authority required (STREAMLINED)

8780

Scleroderma oesophagus

Authority required (STREAMLINED)

8827

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

esomeprazole 20 mg enteric tablet, 30

8600P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] APO-Esomeprazole [TY]	[a] Esomeprazole GH [GQ]
					[a] Esomeprazole GxP [AF]	[a] Esomeprazole Mylan [AL]
					[a] Esomeprazole RBX [RA]	[a] Esomeprazole Viatris [MQ]
					[a] Esopreze [BG]	[a] Nexazole [RW]
					[a] Nexole [RF]	[a] NOUMED ESOMEPRAZOLE [VO]
		[B]7.00	24.76	19.21	[a] Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

10343J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] Noxicid Caps [AL]

▪ ESOMEPRAZOLE

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

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

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

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

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

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

esomeprazole 20 mg enteric tablet, 30

11692J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] APO-Esomeprazole [TY]	[a] Esomeprazole GH [GQ]
					[a] Esomeprazole GxP [AF]	[a] Esomeprazole Mylan [AL]
					[a] Esomeprazole RBX [RA]	[a] Esomeprazole Viatris [MQ]
					[a] Esopreze [BG]	[a] Nexazole [RW]
					[a] Nexole [RF]	[a] NOUMED ESOMEPRAZOLE [VO]
		[B]7.00	24.76	19.21	[a] Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

11687D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] Noxicid Caps [AL]

▪ ESOMEPRAZOLE

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

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

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

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

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

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

esomeprazole 20 mg enteric tablet, 30

8886Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	17.76	19.21	[a] APO-Esomeprazole [TY]	[a] Esomeprazole GH [GQ]
					[a] Esomeprazole GxP [AF]	[a] Esomeprazole Mylan [AL]
					[a] Esomeprazole RBX [RA]	[a] Esomeprazole Viatris [MQ]
					[a] Esopreze [BG]	[a] Nexazole [RW]
					[a] Nexole [RF]	[a] NOUMED ESOMEPRAZOLE [VO]
		[B]7.00	24.76	19.21	[a] Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

10295W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	17.76	19.21	[a] Noxicid Caps [AL]

▪ ESOMEPRAZOLE

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

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

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

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

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

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

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

Authority required

Complex gastro-oesophageal reflux disease (GORD)

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

Treatment criteria:

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

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR

- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

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

esomeprazole 20 mg enteric tablet, 30

12287Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] APO-Esomeprazole [TY]	[a] Esomeprazole GH [GQ]
					[a] Esomeprazole GxP [AF]	[a] Esomeprazole Mylan [AL]
					[a] Esomeprazole RBX [RA]	[a] Esomeprazole Viatris [MQ]
					[a] Esopreze [BG]	[a] Nexazole [RW]
					[a] Nexole [RF]	[a] NOUMED ESOMEPRAZOLE [VO]
		[B]14.00	*36.07	23.52	[a] Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

12275C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] Noxicid Caps [AL]

▪ ESOMEPRAZOLE

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

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

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

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

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

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

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

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

Authority required

Complex gastro-oesophageal reflux disease (GORD)

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

Treatment criteria:

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

Clinical criteria:

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

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

esomeprazole 40 mg enteric tablet, 30

12283L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*28.07	29.52	[a] APO-Esomeprazole [TY]	[a] Esomeprazole GH [GQ]
					[a] Esomeprazole GxP [AF]	[a] Esomeprazole Mylan [AL]
					[a] Esomeprazole RBX [RA]	[a] Esomeprazole Viatris [MQ]
					[a] Esopreze [BG]	[a] Nexazole [RW]
					[a] Nexole [RF]	[a] NOUMED ESOMEPRAZOLE [VO]
		[B]14.00	*42.07	29.52	[a] Nexium [AP]	

esomeprazole 40 mg enteric capsule, 30

12290W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*28.07	29.52	[a] Noxicid Caps [AL]

▪ LANSOPRAZOLE

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

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

lansoprazole 15 mg enteric capsule, 30

8198L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.37	18.82	Zopral [AF]

lansoprazole 15 mg orally disintegrating tablet, 28

9331D

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.29	18.74	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
		[B]4.65	21.94	18.74	[a] Zoton FasTabs [PF]	

▪ LANSOPRAZOLE

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

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

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

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

Authority required (STREAMLINED)

8780

Scleroderma oesophagus

lansoprazole 30 mg orally disintegrating tablet, 28

9478W

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.28	19.73	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
		[B]5.23	23.51	19.73	[a] Zoton FasTabs [PF]	

lansoprazole 30 mg enteric capsule, 28

2241Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.28	19.73	[a] APO-Lansoprazole [TX] [a] NOUMED LANSOPRAZOLE [VO]	[a] Lanzopran [RA] [a] Zopral [AF]

▪ LANSOPRAZOLE

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

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

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

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

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

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

lansoprazole 30 mg orally disintegrating tablet, 28

11697P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.28	19.73	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
		[B]5.23	23.51	19.73	[a] Zoton FasTabs [PF]	

lansoprazole 30 mg enteric capsule, 28

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.28	19.73	[a] APO-Lansoprazole [TX]	[a] Lanzopran [RA]

11669E NP		[a] NOUMED LANSOPRAZOLE [VO]	[a] Zopral [AF]

▪ LANSOPRAZOLE

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

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

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

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

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

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

lansoprazole 30 mg orally disintegrating tablet, 28

9477T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	18.28	19.73	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
			[B]5.23	23.51	19.73	[a] Zoton FasTabs [PF]	

lansoprazole 30 mg enteric capsule, 28

2240X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	18.28	19.73	[a] APO-Lansoprazole [TX] [a] NOUMED LANSOPRAZOLE [VO]	[a] Lanzopran [RA] [a] Zopral [AF]

▪ LANSOPRAZOLE

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

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

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

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

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

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

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

Authority required

Complex gastro-oesophageal reflux disease (GORD)

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

Treatment criteria:

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

Clinical criteria:

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

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

lansoprazole 30 mg orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12276D	2	5	..	*23.11	24.56	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
			[B]10.46	*33.57	24.56	[a] Zoton FasTabs [PF]	

lansoprazole 30 mg enteric capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12284M	2	5	..	*23.11	24.56	[a] APO-Lansoprazole [TX] [a] NOUMED LANSOPRAZOLE [VO]	[a] Lanzopran [RA] [a] Zopral [AF]

▪ OMEPRAZOLE

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

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

omeprazole 10 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8332M NP	1	5	..	17.37	18.82	Losec Tablets [PB]

▪ OMEPRAZOLE

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

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

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

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

Authority required (STREAMLINED)

8780

Scleroderma oesophagus

Authority required (STREAMLINED)

8866

Zollinger-Ellison syndrome

omeprazole 20 mg enteric capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1327W NP	1	5	..	17.76	19.21	[a] APO-Omeprazole [TX] [a] Omeprazole Sandoz [HX] [a] Pharmacor Omeprazole 20 [CR]	[a] Maxor [AF] [a] Pemzo [RW] [a] Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8333N NP	1	5	..	17.76	19.21	[a] APO-Omeprazole [TX] [a] Ozmep [RW]	[a] Maxor EC Tabs [AF]

omeprazole 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9110L NP	1	5	..	17.76	19.21	[a] Acimax Tablets [FJ] [a] Omeprazole Sandoz [SZ]	[a] Omepral [FQ]
			[B]7.15	24.91	19.21	[a] Losec Tablets [PB]	

▪ OMEPRAZOLE

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

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

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

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

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

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

omeprazole 20 mg enteric capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11682W NP	1	5	..	17.76	19.21	[a] APO-Omeprazole [TX] [a] Omeprazole Sandoz [HX] [a] Pharmacor Omeprazole 20 [CR]	[a] Maxor [AF] [a] Pemzo [RW] [a] Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11677N NP	1	5	..	17.76	19.21	[a] Acimax Tablets [FJ] [a] Omeprazole Sandoz [SZ]	[a] Omepral [FQ]
			[B]7.15	24.91	19.21	[a] Losec Tablets [PB]	

omeprazole 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11683X NP	1	5	..	17.76	19.21	[a] APO-Omeprazole [TX] [a] Ozmep [RW]	[a] Maxor EC Tabs [AF]

▪ OMEPRAZOLE

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

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

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

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

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

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

omeprazole 20 mg enteric capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1326T NP	1	1	..	17.76	19.21	[a] APO-Omeprazole [TX] [a] Omeprazole Sandoz [HX] [a] Pharmacor Omeprazole 20 [CR]	[a] Maxor [AF] [a] Pemzo [RW] [a] Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8331L NP	1	1	..	17.76	19.21	[a] APO-Omeprazole [TX] [a] Ozmep [RW]	[a] Maxor EC Tabs [AF]

omeprazole 20 mg enteric tablet, 30

9109K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	17.76	19.21	[a] Acimax Tablets [FJ] [a] Omeprazole Sandoz [SZ]	[a] Omepral [FQ]
		[B]7.15	24.91	19.21	[a] Losec Tablets [PB]	

▪ OMEPRAZOLE

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

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

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

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

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

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

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

Authority required

Complex gastro-oesophageal reflux disease (GORD)

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

Treatment criteria:

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

Clinical criteria:

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

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

omeprazole 20 mg enteric capsule, 30

12281J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] APO-Omeprazole [TX] [a] Omeprazole Sandoz [HX] [a] Pharmacor Omeprazole 20 [CR]	[a] Maxor [AF] [a] Pemzo [RW] [a] Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

12270T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] Acimax Tablets [FJ] [a] Omeprazole Sandoz [SZ]	[a] Omepral [FQ]
		[B]14.30	*36.37	23.52	[a] Losec Tablets [PB]	

omeprazole 20 mg enteric tablet, 30

12272X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] APO-Omeprazole [TX] [a] Ozmep [RW]	[a] Maxor EC Tabs [AF]

▪ PANTOPRAZOLE

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

Restricted benefit
Gastro-oesophageal reflux disease
Restricted benefit
Scleroderma oesophagus
Restricted benefit
Zollinger-Ellison syndrome

pantoprazole 20 mg enteric tablet, 30

8399C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Pantoprazole [TX]	[a] BTC Pantoprazole [BG]
					[a] NOUMED PANTOPRAZOLE [VO]	[a] Ozpan [RA]
					[a] Panthron [ZS]	[a] Pantoprazole APOTEX [TY]
					[a] Pantoprazole generichealth [HQ]	[a] Pantoprazole Sandoz [SZ]
					[a] Salpraz [AF]	[a] Somac [NQ]
					[a] Sozol [RW]	

▪ PANTOPRAZOLE

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

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

pantoprazole 40 mg enteric coated granules, 30 sachets

9424B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	34.58	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

8008L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.55	18.00	[a] APO-Pantoprazole [TX]	[a] APX-PANTOPRAZOLE [TW]
					[a] BTC Pantoprazole [BG]	[a] I-Pantoprazole [CR]
					[a] NOUMED PANTOPRAZOLE [VO]	[a] Ozpan [RA]
					[a] Panthron [ZS]	[a] Pantoprazole APOTEX [TY]
					[a] Pantoprazole generichealth [HQ]	[a] Pantoprazole Sandoz [SZ]
					[a] Salpraz [AF]	[a] Somac [NQ]
					[a] Sozol [RW]	

▪ PANTOPRAZOLE

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

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

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

pantoprazole 40 mg enteric coated granules, 30 sachets

11678P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	34.58	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

11681T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.55	18.00	[a] APO-Pantoprazole [TX]	[a] APX-PANTOPRAZOLE [TW]
					[a] BTC Pantoprazole [BG]	[a] I-Pantoprazole [CR]
					[a] NOUMED PANTOPRAZOLE [VO]	[a] Ozpan [RA]

[a] Panthron [ZS]	[a] Pantoprazole APOTEX [TY]
[a] Pantoprazole generichealth [HQ]	[a] Pantoprazole Sandoz [SZ]
[a] Salpraz [AF]	[a] Somac [NQ]
[a] Sozol [RW]	

▪ PANTOPRAZOLE

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

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

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

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

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

pantoprazole 40 mg enteric coated granules, 30 sachets

9423Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	34.58	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

8007K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	16.55	18.00	[a] APO-Pantoprazole [TX]	[a] APX-PANTOPRAZOLE [TW]
					[a] BTC Pantoprazole [BG]	[a] I-Pantoprazole [CR]
					[a] NOUMED PANTOPRAZOLE [VO]	[a] Ozpan [RA]
					[a] Panthron [ZS]	[a] Pantoprazole APOTEX [TY]
					[a] Pantoprazole generichealth [HQ]	[a] Pantoprazole Sandoz [SZ]
					[a] Salpraz [AF]	[a] Somac [NQ]
					[a] Sozol [RW]	

▪ PANTOPRAZOLE

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

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

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

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

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

Authority required

Complex gastro-oesophageal reflux disease (GORD)

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

Treatment criteria:

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

Clinical criteria:

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

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

pantoprazole 40 mg enteric coated granules, 30 sachets

12282K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*55.71	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

12277E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*19.65	21.10	[a] APO-Pantoprazole [TX]	[a] APX-PANTOPRAZOLE [TW]
					[a] BTC Pantoprazole [BG]	[a] I-Pantoprazole [CR]
					[a] NOUMED PANTOPRAZOLE [VO]	[a] Ozpan [RA]
					[a] Panthron [ZS]	[a] Pantoprazole APOTEX [TY]
					[a] Pantoprazole generichealth [HQ]	[a] Pantoprazole Sandoz [SZ]
					[a] Salpraz [AF]	[a] Somac [NQ]
					[a] Sozol [RW]	

▪ RABEPRAZOLE

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

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

rabeprazole sodium 10 mg enteric tablet, 28

8507R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.20	18.65	[a] APO-Rabeprazole [TX]	[a] Parbezol [RW]
					[a] Rabeprazole Sandoz [SZ]	
		[B]4.85	22.05	18.65	[a] Pariet [JC]	

▪ RABEPRAZOLE

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

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

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

Authority required (STREAMLINED)

8780

Scleroderma oesophagus

rabeprazole sodium 20 mg enteric tablet, 30

8508T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.04	18.49	[a] APO-Rabeprazole [TX]	[a] Noumed Rabeprazole [VO]
					[a] Parbezol [RW]	[a] Rabeprazole Mylan [AF]
					[a] Rabeprazole Sandoz [SZ]	[a] Rabeprazole SUN [RN]
					[a] Zabep [AL]	
		[B]5.01	22.05	18.49	[a] Pariet [JC]	

▪ RABEPRAZOLE

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

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

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

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

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

rabeprazole sodium 20 mg enteric tablet, 30

11670F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.04	18.49	[a] APO-Rabeprazole [TX]	[a] Noumed Rabeprazole [VO]
					[a] Parbezol [RW]	[a] Rabeprazole Mylan [AF]
					[a] Rabeprazole Sandoz [SZ]	[a] Rabeprazole SUN [RN]
					[a] Zabep [AL]	
		[B]5.01	22.05	18.49	[a] Pariet [JC]	

▪ RABEPRAZOLE

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

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

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

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

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

rabeprazole sodium 20 mg enteric tablet, 30

8509W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	17.04	18.49	[a] APO-Rabeprazole [TX]	[a] Noumed Rabeprazole [VO]
					[a] Parbezol [RW]	[a] Rabeprazole Mylan [AF]
					[a] Rabeprazole Sandoz [SZ]	[a] Rabeprazole SUN [RN]
					[a] Zabep [AL]	
		[B]5.01	22.05	18.49	[a] Pariet [JC]	

▪ RABEPRAZOLE

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

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

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

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

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

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

Authority required

Complex gastro-oesophageal reflux disease (GORD)

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

Treatment criteria:

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

Clinical criteria:

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

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

rabeprazole sodium 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12286P	2	5	..	*20.63	22.08	[a] APO-Rabeprazole [TX] [a] Parbezol [RW] [a] Rabeprazole Sandoz [SZ] [a] Zabep [AL]	[a] Noumed Rabeprazole [VO] [a] Rabeprazole Mylan [AF] [a] Rabeprazole SUN [RN]
			[B]10.02	*30.65	22.08	[a] Pariet [JC]	

Combinations for eradication of Helicobacter pylori

▪ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN

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

Restricted benefit

Eradication of Helicobacter pylori

Clinical criteria:

- The condition must be associated with peptic ulcer disease.

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10759G NP	‡1	..	..	38.89	31.60	[a] ESOMEPRAZOLE SANDOZ Hp7 [SZ]

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8738X NP	‡1	..	[B]4.96	43.85	31.60	[a] Nexium Hp7 [AP]

▪ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, tertiary amines

▪ ATROPINE SULFATE

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5022H DP	1	..	..	25.13	26.58	Atropine Injection (Pfizer) [WZ]

▪ ATROPINE SULFATE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1089H NP	1	1	..	25.13	26.58	Atropine Injection (Pfizer) [WZ]

PROPULSIVES

Propulsives

▪ DOMPERIDONE

domperidone 10 mg tablet, 25

1347X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	15.72	17.17	[a] APO-DOMPERIDONE [TX]	[a] Motilium [JT]

▪ METOCLOPRAMIDE

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

1206L (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	21.09	22.54	METOCLOPRAMIDE INJECTION BP [WZ]

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

5153F (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	21.09	22.54	METOCLOPRAMIDE INJECTION BP [WZ]

metoclopramide hydrochloride 10 mg tablet, 25

1207M (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.15	17.60	[a] APO-Metoclopramide [TX] [a] Pramin [AF]	[a] EMEXLON [RW]
		[B]3.55	19.70	17.60	[a] Maxolon [IL]	

metoclopramide hydrochloride 10 mg tablet, 25

5151D (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.15	17.60	[a] APO-Metoclopramide [TX] [a] Pramin [AF]	[a] EMEXLON [RW]
		[B]3.55	19.70	17.60	[a] Maxolon [IL]	

▪ ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS

Serotonin (5HT3) antagonists

▪ FOSNETUPITANT + PALONOSETRON

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

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

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

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

Authority required

Nausea and vomiting

Clinical criteria:

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

fosnetupitant 235 mg + palonosetron 250 microgram injection, 1 vial

13640X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	111.59	31.60	Akynzeo IV [JZ]

▪ GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

granisetron 3 mg/3 mL injection, 3 mL ampoule

8729K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.37	17.82	[a] Granisetron-AFT [AE] [a] Kytril [IX]	[a] Granisetron Kabi [PK]

▪ GRANISETRON

Authority required (STREAMLINED)

4092
Nausea and vomiting
Clinical criteria:
- The condition must be associated with radiotherapy being used to treat malignancy.

granisetron 3 mg/3 mL injection, 3 mL ampoule

8730L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.37	17.82	[a] Granisetron-AFT [AE] [a] Kytril [IX]	[a] Granisetron Kabi [PK]

▪ GRANISETRON

Authority required (STREAMLINED)
10498
Nausea and vomiting
Clinical criteria:
- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with oral chemotherapy being used to treat malignancy.

granisetron 2 mg tablet, 5

8873B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	58.03	31.60	Kytril [IX]

▪ GRANISETRON

Restricted benefit
Nausea and vomiting
Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

granisetron 2 mg tablet, 1

8728J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*31.29	31.60	Kytril [IX]

▪ NETUPITANT + PALONOSETRON

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
Note Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
14443
Nausea and vomiting
Clinical criteria:
- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.

netupitant 300 mg + palonosetron 500 microgram capsule, 1

10731T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	101.26	31.60	Akynzeo [JZ]

▪ ONDANSETRON

Authority required (STREAMLINED)
15193
Nausea and vomiting
Clinical criteria:
- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

ondansetron 4 mg/5 mL oral liquid, 50 mL

8233H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	100.31	31.60	Zofran syrup 50 mL [AS]

ondansetron 4 mg tablet, 10

1594X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	22.87	24.32	[a] APO-Ondansetron [TX] [a] Ondansetron-DRLA [RZ]	[a] APX-Ondansetron [TY] [a] Ondansetron Mylan Tablets [AF]

						[a] Ondansetron SZ [HX]	[a] Ondansetron Tablets Viatris [AL]
						[a] Zofran [AS]	[a] Zotren 4 [RF]

ondansetron 8 mg tablet, 10

1595Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.10	26.55	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
						[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
						[a] Ondansetron SZ [HX]	[a] Ondansetron Tablets Viatris [AL]
						[a] Zofran [AS]	[a] Zotren 8 [RF]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg orally disintegrating tablet, 4

5470X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.37	18.82	[a] APX-Ondansetron ODT [TY]	[a] Ondansetron Mylan ODT [AF]
						[a] Ondansetron ODT-DRLA [RZ]	[a] Ondansetron SZ ODT [HX]
						[a] Zotren ODT [RF]	

ondansetron 8 mg orally disintegrating tablet, 4

5471Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.20	19.65	[a] APX-Ondansetron ODT [TY]	[a] Ondansetron Mylan ODT [AF]
						[a] Ondansetron ODT-DRLA [RZ]	[a] Ondansetron ODT Viatris [AL]
						[a] Ondansetron SZ ODT [HX]	[a] Zotren ODT [RF]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg tablet, 4

8224W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.37	18.82	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
						[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
						[a] Ondansetron SZ [HX]	[a] Ondansetron Tablets Viatris [AL]
						[a] Zofran [AS]	[a] Zotren 4 [RF]

ondansetron 8 mg tablet, 4

8225X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.20	19.65	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
						[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
						[a] Ondansetron SZ [HX]	[a] Ondansetron Tablets Viatris [AL]
						[a] Zofran [AS]	[a] Zotren 8 [RF]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg/5 mL oral liquid, 50 mL

9441X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	100.31	31.60	Zofran syrup 50 mL [AS]

▪ ONDANSETRON

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

Authority required (STREAMLINED)

15193

Nausea and vomiting

Clinical criteria:

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

ondansetron 4 mg orally disintegrating tablet, 10

5472B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	22.87	24.32	[a] APX-Ondansetron ODT [TY] [a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX]	[a] Ondansetron Mylan ODT [AF] [a] Ondansetron ODT Lupin [HQ] [a] Zotren ODT [RF]

ondansetron 4 mg wafer, 10

8412R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]3.46	26.33	24.32	[a] Zofran Zydis [AS]

▪ ONDANSETRON

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

Authority required (STREAMLINED)

15193

Nausea and vomiting

Clinical criteria:

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

ondansetron 8 mg orally disintegrating tablet, 10

5473C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	25.10	26.55	[a] APX-Ondansetron ODT [TY] [a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron ODT Viatris [AL] [a] Zotren ODT [RF]	[a] Ondansetron Mylan ODT [AF] [a] Ondansetron ODT Lupin [HQ] [a] Ondansetron SZ ODT [HX]

ondansetron 8 mg wafer, 10

8413T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]3.45	31.30	29.30	[a] Zofran Zydis [AS]

▪ PALONOSETRON

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

Note This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

palonosetron 250 microgram/5 mL injection, 5 mL vial

5295Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	24.12	25.57	[a] Aloxi [JZ] [a] PALONOSETRON Medsurge [DZ]	[a] Palonosetron Dr.Reddy's [RZ]

Other antiemetics

▪ APREPITANT

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

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

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

Authority required (STREAMLINED)

4211

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**

- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

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

Authority required (STREAMLINED)

4215

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6444

Nausea and vomiting

Clinical criteria:

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

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

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

Authority required (STREAMLINED)

6370

Nausea and vomiting

Clinical criteria:

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

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

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

aprepitant 165 mg capsule, 1

2518M

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	72.78	31.60	[a] Aprepitant APOTEX [TX]	[a] APREPITANT SCP [XC]

▪ FOSAPREPITANT

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

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

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

Authority required (STREAMLINED)

6886

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6891

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6887

Nausea and vomiting

Clinical criteria:

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

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

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

Authority required (STREAMLINED)

6852

Nausea and vomiting

Clinical criteria:

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

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

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

fosaprepitant 150 mg injection, 1 vial

11107N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	87.90	31.60	[a] Emend IV [MK] [a] FOSAPREPITANT MEDSURGE [DZ]	[a] FOSAPREPITANT-AFT [AE] [a] FOSAPREPITANT MSN [RQ]

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules

5206B (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.78	25.23	Stemetil [SW]

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

Note Pharmaceutical benefits that have the form prochlorperazine maleate, 5 mg tablet can be substituted for prochlorperazine maleate 5 mg tablet Stemetil (Ireland) in the case of a shortage.

prochlorperazine maleate 5 mg tablet, 250

14108M (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.1	..	..	*33.78	31.60	[a] Stemetil (Ireland) [OJ]

prochlorperazine maleate 5 mg tablet, 25

5205Y (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.37	17.82	[a] APO-Prochlorperazine [TX] [a] Prochlorperazine GH [GQ]	[a] ProCalm [RW]
		[B]2.79	19.16	17.82	[a] Stemetil [SW]	

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

Note As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules

2369Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.78	25.23	Stemetil [SW]

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

Note As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

Note Pharmaceutical benefits that have the form prochlorperazine maleate, 5 mg tablet can be substituted for prochlorperazine maleate 5 mg tablet Stemetil (Ireland) in the case of a shortage.

prochlorperazine maleate 5 mg tablet, 250

14129P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.1	..	..	*33.78	31.60	[a] Stemetil (Ireland) [OJ]

prochlorperazine maleate 5 mg tablet, 25

2893G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.37	17.82	[a] APO-Prochlorperazine [TX] [a] Prochlorperazine GH [GQ]	[a] ProCalm [RW]
		[B]2.79	19.16	17.82	[a] Stemetil [SW]	

▪ PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

3374N DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*36.65	31.60	DBL Promethazine Hydrochloride [PF]

▪ BILE AND LIVER THERAPY

BILE THERAPY

Bile acids and derivatives

▪ OBETICHOLIC ACID

Caution Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

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

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

Note Special Pricing Arrangements apply.

Note Laboratory readings requested in this authority application must be no older than 52 weeks.

Authority required (STREAMLINED)

12138

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of: (i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

Clinical criteria:

- Patient must have achieved an adequate response to this drug, defined as having at least one of: (i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.

The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records.

obeticholic acid 5 mg tablet, 30

12630R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3793.60	31.60	Ocaliva [EU]

obeticholic acid 10 mg tablet, 30

12640G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3793.60	31.60	Ocaliva [EU]

▪ OBETICHOLIC ACID

Caution Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

Note Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

Note In accordance with the dosing directions in the approved Product Information, the 10 mg presentation is not PBS listed for initiation of treatment.

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

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

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

Note Special Pricing Arrangements apply.

Note Laboratory readings requested in this authority application must be no older than 52 weeks.

Authority required

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

Clinical criteria:

- Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug, **AND**
- Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised, **AND**
- Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid.

Population criteria:

- Patient must be aged 18 years or older.

Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction.

obeticholic acid 5 mg tablet, 30

12623J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3793.60	31.60	Ocaliva [EU]

▪ URSODEOXYCHOLIC ACID

Note Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

9032

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

ursodeoxycholic acid 250 mg capsule, 100

8448P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*227.77	31.60	[a] APO-Ursodeoxycholic acid [TX] [a] Ursofalk [FD]	[a] Ursodox GH [GQ] [a] Ursosan [BZ]

ursodeoxycholic acid 500 mg tablet, 100

11180K

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	296.35	31.60	Ursofalk [FD]

▪ DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

▪ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

bisacodyl 5 mg enteric tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1259G NP	1	2	..	17.87	19.32	Lax-Tab [AE]

▪ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Terminal malignant neoplasia

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Anorectal congenital abnormalities

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Megacolon

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

bisacodyl 10 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1260H NP	3	5	..	*26.10	27.55	[a] Petrus Bisacodyl Suppositories [PP]
			[B]1.29	*27.39	27.55	[a] Dulcolax [VZ]

bisacodyl 10 mg suppository, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1258F NP	3	4	..	*24.75	26.20	Petrus Bisacodyl Suppositories [PP]

Osmotically acting laxatives

▪ MACROGOL-3350

Restricted benefit
Constipation
Clinical criteria:
- Patient must have malignant neoplasia.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be receiving palliative care.

Restricted benefit
Chronic constipation
Clinical criteria:
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

Restricted benefit
Faecal impaction
Clinical criteria:
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

macrogol-3350 1 g/g powder for oral liquid, 510 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3416T NP	‡1	5	..	22.93	24.38	OsmoLax [KY]

▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

Restricted benefit
Constipation
Clinical criteria:
- Patient must have malignant neoplasia.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be receiving palliative care.

Restricted benefit
Chronic constipation
Clinical criteria:
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

Restricted benefit
Faecal impaction
Clinical criteria:
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8612G NP	‡1	5	..	21.03	22.48	[a] APOHEALTH Macrogol with Electrolytes [GX]	[a] APO-MACROGOL plus ELECTROLYTES [TX]

			[a] Chemists' Own Macrogol with Electrolytes [RW]	[a] Macrovic [RF]
			[a] Molaxole [GO]	
[B]2.12	23.15	22.48	[a] Movicol [NE]	

Enemas

▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

Restricted benefit
Constipation
Clinical criteria:
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit
Constipation
Clinical criteria:
- Patient must be receiving palliative care.

Restricted benefit
Terminal malignant neoplasia
Restricted benefit
Anorectal congenital abnormalities
Restricted benefit
Megacolon

sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL

2091C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*37.21	31.60	Micolette [AE]

NP

▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

INTESTINAL ANTIINFECTIVES

Antibiotics

▪ NYSTATIN

nystatin 500 000 units capsule, 50

1699K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	22.63	24.08	Nilstat [AS]

NP

nystatin 500 000 units capsule, 50

3345C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	22.63	24.08	Nilstat [AS]

DP

nystatin 500 000 units tablet, 50

1696G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	22.63	24.08	Nilstat [AS]

NP

nystatin 500 000 units tablet, 50

3342X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	22.63	24.08	Nilstat [AS]

DP

▪ RIFAXIMIN

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

Authority required
Prevention of hepatic encephalopathy
Treatment criteria:
- Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

Clinical criteria:

- The treatment must be in combination with lactulose, if lactulose is tolerated, **AND**
- Patient must have had prior episodes of hepatic encephalopathy.

rifaximin 550 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10001J	1	5	..	453.43	31.60	Xifaxan [NE]

▪ VANCOMYCIN

Note Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

Authority required

Antibiotic associated pseudomembranous colitis

Clinical criteria:

- The condition must be due to **Clostridium difficile**, **AND**
- The condition must be unresponsive to metronidazole.

Authority required

Antibiotic associated pseudomembranous colitis

Clinical criteria:

- The condition must be due to **Clostridium difficile**, **AND**
- Patient must have an intolerance to metronidazole.

vancomycin 125 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3113W	2	..	..	*122.91	31.60	[a] Vancocin [AS]	[a] Vancomycin BNM 125mg [BZ]

vancomycin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3114X	2	..	..	*237.31	31.60	[a] Vancocin [AS]	[a] Vancomycin BNM 250mg [BZ]

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3196F						
NP	‡1	..	..	18.27	19.72	O.R.S. [AF]

▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

Authority required

Rehydration in intestinal failure

sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11049M	30	..	..	*159.87	31.60	O.R.S. [AF]

ANTIPROPULSIVES

Antipropulsives

▪ DIPHENOXYLATE + ATROPINE SULFATE

diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2501P						
NP	1	..	..	16.37	17.82	[a] Lofenoxal [IL]
			[B]3.33	19.70	17.82	[a] Lomotil [IM]

▪ LOPERAMIDE

Authority required (STREAMLINED)

6364

Diarrhoea

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

loperamide hydrochloride 2 mg capsule, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1571Q NP	1	..	..	14.95	16.40	[a] Gastrex [CR]	[a] Gastro-Stop [AS]

▪ LOPERAMIDE

Authority required

Diarrhoea

loperamide hydrochloride 2 mg capsule, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10889D NP	5	..	..	*20.92	22.37	[a] Gastrex [CR]	[a] Gastro-Stop [AS]

INTESTINAL ANTIINFLAMMATORY AGENTS

Corticosteroids acting locally

▪ BUDESONIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

budesonide 2 mg/application foam, 2 x 14 applications

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10034D NP	1	3	..	151.92	31.60	Budenofalk [FD]

▪ BUDESONIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

12607

Mild to moderate Crohn disease

Clinical criteria:

- The condition must affect the ileum; OR
- The condition must affect the ascending colon; OR
- The condition must affect the ileum and ascending colon.

The total duration of therapy should be no more than 12 weeks in any single course.

budesonide 3 mg modified release capsule, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12915R NP	1	2	..	55.23	31.60	Entocort [EU]

▪ BUDESONIDE

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Subsequent continuing treatment - Maintenance of remission

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have documented evidence of having achieved histologic remission while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm^2 hpf on oesophageal biopsy, **AND**
- The condition must not have progressed while being treated with this drug.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types.

Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.

The result of the histological assessment must be documented in the patient's medical records.

First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.

budesonide 500 microgram orally disintegrating tablet, 60

12987M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	414.88	31.60	Jorveza [FD]

budesonide 1 mg orally disintegrating tablet, 60

12982G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	414.88	31.60	Jorveza [FD]

▪ BUDESONIDE

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment - Induction of remission

Clinical criteria:

- Patient must have a history of symptoms of oesophageal dysfunction, **AND**
- Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm^2 hpf, **AND**
- Patient must not receive more than 90 days of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis.

Applications for treatment of this condition must be received within 12 weeks of biopsy.

Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation.

Diagnostic sensitivity increases with the number of biopsies and can be optimised, where necessary, by taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

After prescribing the Initial induction treatment with budesonide, a histologic assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing therapy.

The histologic assessment should be conducted no later than 2 weeks prior to completing the PBS-subsidised First continuing maintenance treatment course to avoid an interruption of supply for continuing therapy.

budesonide 1 mg orally disintegrating tablet, 90

12994X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	618.10	31.60	Jorveza [FD]

▪ BUDESONIDE

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Eosinophilic oesophagitis

Treatment Phase: First continuing treatment - until remission is confirmed

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 36 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types.

Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.

The result of the histological assessment must be documented in the patient's medical records.

First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.

budesonide 500 microgram orally disintegrating tablet, 60

13719C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	8	..	414.88	31.60	Jorveza [FD]

budesonide 1 mg orally disintegrating tablet, 60

13711P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	8	..	414.88	31.60	Jorveza [FD]

▪ HYDROCORTISONE ACETATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

hydrocortisone acetate 10% enema, 21.1 g

1502C

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*43.05	31.60	Colifoam [GO]

▪ PREDNISOLONE SODIUM PHOSPHATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL

1920C

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	3	..	*182.51	31.60	Predsol [AS]

▪ PREDNISOLONE SODIUM PHOSPHATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

prednisolone (as sodium phosphate) 5 mg suppository, 10

2554K

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	3	..	*40.77	31.60	Predsol [AS]

Aminosalicylic acid and similar agents

▪ BALSALAZIDE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7621

Ulcerative colitis

Clinical criteria:

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

balsalazide sodium 750 mg capsule, 280

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11351K NP	1	5	..	119.55	31.60	Colazide [PK]

▪ BALSALAZIDE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14306

Ulcerative colitis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

balsalazide sodium 750 mg capsule, 280

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13484Q NP	2	5	..	*230.65	31.60	Colazide [PK]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Ulcerative colitis

mesalazine 1.5 g modified release granules, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9206M NP	1	5	..	101.66	31.60	Salofalk [FD]

mesalazine 500 mg modified release granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8598M NP	2	5	..	*123.13	31.60	Salofalk [FD]

mesalazine 800 mg enteric tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11210B NP	1	5	..	79.11	31.60	Asacol [EU]

mesalazine 4 g modified release granules, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10254Q NP	1	5	..	129.37	31.60	Pentasa [FP]

mesalazine 3 g modified release granules, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10257W NP	1	5	..	101.66	31.60	Salofalk [FD]

mesalazine 1 g modified release granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8599N NP	1	5	..	115.65	31.60	Salofalk [FD]

mesalazine 1.6 g enteric tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12463Y NP	2	4	..	*153.69	31.60	Asacol [EU]

▪ MESALAZINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Ulcerative colitis

Restricted benefit

Crohn disease

mesalazine 2 g modified release granules, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2287J NP	1	5	..	129.37	31.60	Pentasa [FP]

mesalazine 1 g modified release tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3413P NP	2	5	..	*137.09	31.60	Pentasa [FP]

mesalazine 250 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1611T NP	1	5	..	45.10	31.60	Mesasal [GO]

mesalazine 500 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8731M NP	2	5	..	*123.13	31.60	Salofalk [FD]

mesalazine 500 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2214M NP	2	5	..	*123.13	31.60	Pentasa [FP]

mesalazine 1 g modified release granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12203G NP	1	5	..	106.97	31.60	Pentasa [FP]

mesalazine 1 g enteric tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11554D NP	2	5	..	*137.75	31.60	Salofalk [FD]

▪ MESALAZINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Ulcerative colitis

Clinical criteria:

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

Restricted benefit

Crohn disease

Clinical criteria:

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

mesalazine 2 g modified release granules, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13397D NP	2	5	..	*250.27	31.60	Pentasa [FP]

mesalazine 1 g modified release tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13576M NP	4	5	..	*265.71	31.60	Pentasa [FP]

mesalazine 250 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13423L NP	2	5	..	*76.75	31.60	Mesasal [GO]

mesalazine 500 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13362G NP	4	5	..	*237.79	31.60	Salofalk [FD]

mesalazine 500 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13396C NP	4	5	..	*237.79	31.60	Pentasa [FP]

mesalazine 1 g modified release granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13355X NP	2	5	..	*204.83	31.60	Pentasa [FP]

mesalazine 1 g enteric tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13394Y NP	4	5	..	*267.07	31.60	Salofalk [FD]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Ulcerative colitis

Clinical criteria:

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

mesalazine 1.5 g modified release granules, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13460K NP	2	5	..	*193.69	31.60	Salofalk [FD]

mesalazine 500 mg modified release granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13361F NP	4	5	..	*237.79	31.60	Salofalk [FD]

mesalazine 800 mg enteric tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13422K NP	2	5	..	*146.33	31.60	Asacol [EU]

mesalazine 4 g modified release granules, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13456F NP	2	5	..	*250.27	31.60	Pentasa [FP]

mesalazine 3 g modified release granules, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13518L NP	2	5	..	*193.69	31.60	Salofalk [FD]

mesalazine 1 g modified release granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13398E NP	2	5	..	*222.85	31.60	Salofalk [FD]

mesalazine 1.6 g enteric tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13395B NP	4	4	..	*298.95	31.60	Asacol [EU]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

Restricted benefit

Ulcerative colitis

mesalazine 1.2 g modified release tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13247F NP	1	5	..	173.58	31.60	[a] MESALZ [RA]

mesalazine 1.2 g modified release tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9353G NP	2	5	..	*173.59	31.60	[a] Mesalazine 1.2 TAKEDA [NQ]	[a] Mezavant [TK]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

Restricted benefit

Ulcerative colitis

Clinical criteria:

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

mesalazine 1.2 g modified release tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13356Y NP	2	5	..	*338.71	31.60	[a] MESALZ [RA]

mesalazine 1.2 g modified release tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13487W NP	4	5	..	*338.71	31.60	[a] Mesalazine 1.2 TAKEDA [NQ]	[a] Mezavant [TK]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

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

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

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Acute episode of mild to moderate ulcerative proctitis

mesalazine 1 g suppository, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12198B NP	1	1	..	83.13	31.60	Pentasa [FP]

mesalazine 1 g suppository, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5461K NP	1	1	..	99.83	31.60	Salofalk [FD]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

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

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

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4888

Acute episode of mild to moderate ulcerative colitis

mesalazine 1 g/100 mL enema, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8753Q NP	4	1	..	*215.27	31.60	Pentasa [FP]

mesalazine 2 g/60 mL enema, 7 x 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8616L NP	4	1	..	*215.27	31.60	Salofalk [FD]

mesalazine 4 g/60 mL enema, 7 x 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8617M NP	4	1	..	*331.99	31.60	Salofalk [FD]

mesalazine 1 g/application foam, 14 applications

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8768L NP	4	1	..	*247.83	31.60	Salofalk [FD]

▪ OLSALAZINE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4824

Ulcerative colitis

Clinical criteria:

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

olsalazine sodium 250 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1728Y NP	1	5	..	45.05	31.60	Dipentum [IX]

olsalazine sodium 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8086N NP	1	5	..	69.10	31.60	Dipentum [IX]

▪ SULFASALAZINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

sulfasalazine 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2093E NP	2	5	..	*52.83	31.60	Salazopyrin [PF]

sulfasalazine 500 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2096H NP	2	5	..	*56.81	31.60	[a] Pyralin EN [FZ]
			[B]4.00	*60.81	31.60	[a] Salazopyrin-EN [PF]

▪ SULFASALAZINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

sulfasalazine 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13557M NP	4	5	..	*92.19	31.60	Salazopyrin [PF]

sulfasalazine 500 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13433B NP	4	5	..	*100.15	31.60	[a] Pyralin EN [FZ]
			[B]8.00	*108.15	31.60	[a] Salazopyrin-EN [PF]

▪ DIGESTIVES, INCL. ENZYMES

DIGESTIVES, INCL. ENZYMES

Enzyme preparations

▪ PANCREATIC EXTRACT

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

pancreatic extract 10 000 units modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8020D NP	5	10	..	*145.92	31.60	Creon 10,000 [GO]

pancreatic extract 25 000 units modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8021E NP	2	10	..	*118.03	31.60	Creon 25,000 [GO]

pancreatic extract 5000 units/100 mg enteric coated granules, 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5453B NP	3	10	..	*113.43	31.60	Creon Micro [GO]

pancreatic extract 35 000 units modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12595X NP	2	10	..	*161.85	31.60	Creon 35,000 [GO]

▪ PANCREATIC EXTRACT

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

pancreatic extract 10 000 units modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13560Q NP	10	10	..	*283.37	31.60	Creon 10,000 [GO]

pancreatic extract 25 000 units modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13470Y NP	4	10	..	*227.63	31.60	Creon 25,000 [GO]

pancreatic extract 5000 units/100 mg enteric coated granules, 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13375Y NP	6	10	..	*218.37	31.60	Creon Micro [GO]

pancreatic extract 35 000 units modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13407P NP	4	10	..	*315.23	31.60	Creon 35,000 [GO]

▪ DRUGS USED IN DIABETES

INSULINS AND ANALOGUES

Insulins and analogues for injection, fast-acting

▪ INSULIN ASPART

insulin aspart 100 units/mL fast acting injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13651L NP	5	1	..	*167.52	31.60	Fiasp Penfill [NO]

insulin aspart 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8571D NP	5	2	..	*101.27	31.60	NovoRapid [NO]

insulin aspart 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8435Y NP	5	1	..	*167.52	31.60	NovoRapid Penfill 3 mL [NO]

insulin aspart 100 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12254Y NP	5	1	..	*167.52	31.60	NovoRapid FlexPen [NF]

▪ INSULIN GLULISINE

insulin glulisine 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9224L NP	5	2	..	*101.27	31.60	Apidra [SW]

insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1921D NP	5	1	..	*167.57	31.60	Apidra [AV]

insulin glulisine 100 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12268Q NP	5	1	..	*167.57	31.60	Apidra SoloStar [SW]

▪ INSULIN LISPRO

insulin lispro 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8084L NP	5	2	..	*101.27	31.60	Humalog [LY]

insulin lispro 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8212F NP	5	1	..	*167.52	31.60	Humalog [LY]

insulin lispro 200 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11645X NP	5	1	..	*266.87	31.60	Humalog U200 Kwikpen [LY]

insulin lispro 100 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12237C NP	5	1	..	*167.52	31.60	Humalog KwikPen [KP]

▪ INSULIN NEUTRAL HUMAN

insulin neutral human 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1531N NP	5	2	..	*86.57	31.60	Actrapid [NO]	Humulin R [LY]

insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1762R NP	5	1	..	*141.07	31.60	Actrapid Penfill 3 mL [NO]	Humulin R [LY]

Insulins and analogues for injection, intermediate-acting

▪ INSULIN ISOPHANE HUMAN

insulin isophane human 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1533Q NP	5	2	..	*86.57	31.60	Humulin NPH [LY]	Protaphane [NO]

insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1761Q NP	5	1	..	*141.07	31.60	Humulin NPH [LY]	Protaphane Penfill 3 mL [NO]

insulin isophane human 100 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12262J NP	5	1	..	*141.07	31.60	Protaphane InnoLet [NI]

Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting

▪ INSULIN ASPART + INSULIN ASPART PROTAMINE

insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8609D NP	5	1	..	*167.52	31.60	NovoMix 30 Penfill 3 mL [NO]

insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12238D NP	5	1	..	*167.52	31.60	NovoMix 30 FlexPen [NF]

▪ INSULIN DEGLUDEC + INSULIN ASPART

Note Special Pricing Arrangements apply.

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11417X NP	5	1	..	*381.02	31.60	Ryzodeg Flextouch [NO]

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11426J NP	5	1	..	*381.02	31.60	Ryzodeg Penfill [NO]

▪ INSULIN LISPRO + INSULIN LISPRO PROTAMINE

insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8390N NP	5	1	..	*167.52	31.60	Humalog Mix25 [LY]

insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8874C NP	5	1	..	*167.52	31.60	Humalog Mix50 [LY]

insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12261H NP	5	1	..	*167.52	31.60	Humalog Mix50 KwikPen [KP]

insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12234X NP	5	1	..	*167.52	31.60	Humalog Mix25 KwikPen [KP]

▪ INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN

insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1426C NP	5	2	..	*86.57	31.60	Humulin 30/70 [LY]

insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1763T NP	5	1	..	*141.07	31.60	Humulin 30/70 [LY]	Mixtard 30/70 Penfill 3 mL [NO]

insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12255B NP	5	1	..	*141.07	31.60	Mixtard 30/70 InnoLet [NI]

Insulins and analogues for injection, long-acting

▪ INSULIN DETEMIR

Note Special Pricing Arrangements apply.

Restricted benefit
Type 1 diabetes

insulin detemir 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9040T NP	5	1	..	*356.22	31.60	Levemir Penfill [NO]

insulin detemir 100 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12236B NP	5	1	..	*356.22	31.60	Levemir FlexPen [NF]

▪ INSULIN GLARGINE

insulin glargine 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9039R NP	5	1	..	*187.42	31.60	Optisulin [GZ]

insulin glargine 100 units/mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11815W NP	5	1	..	*187.42	31.60	Optisulin SoloStar [WA]

▪ INSULIN GLARGINE

Note Special Pricing Arrangements apply.

insulin glargine 300 units/mL injection, 3 x 1.5 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11308E NP	5	1	..	*255.97	31.60	Toujeo Solostar [SW]

insulin glargine 300 units/mL injection, 5 x 1.5 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11302W NP	5	1	..	*420.87	31.60	Toujeo Solostar [SW]

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Biguanides

▪ METFORMIN

metformin hydrochloride 1 g tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8607B NP	1	5	..	17.76	19.21	[a] APX-Metformin [TY]	[a] Blooms The Chemist Metformin 1000 mg [BG]
						[a] Diaformin 1000 [AF]	[a] Formet 1000 [RW]
						[a] Glucobete 1000 [ZS]	[a] Metformin GH [HQ]
						[a] Metformin Sandoz [SZ]	
			[B]4.89	22.65	19.21	[a] Diabex 1000 [AL]	

metformin hydrochloride 1 g modified release tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3439B NP	1	5	..	17.76	19.21	[a] APO-Metformin XR 1000 [TX]	[a] Blooms the Chemist Metformin XR 1000 [IB]
						[a] Diaformin XR 1000 [AF]	[a] METEX XR [RF]
						[a] Pharmacor Metformin XR [CR]	
			[B]5.34	23.10	19.21	[a] Diabex XR 1000 [AL]	

metformin hydrochloride 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2430X NP	1	5	..	16.69	18.14	[a] APX-Metformin [TY]	[a] Blooms The Chemist Metformin 500 mg [BG]
						[a] Diaformin [AF]	[a] FORMET 500 [RF]
						[a] Glucobete 500 [ZS]	[a] Metformin GH [HQ]
						[a] Metformin Sandoz [SZ]	
			[B]5.47	22.16	18.14	[a] Diabex [AL]	

metformin hydrochloride 500 mg modified release tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9435N NP	1	5	..	17.76	19.21	[a] APO-Metformin XR 500 [TX]	[a] Blooms the Chemist Metformin XR 500 [IB]
						[a] Metex XR [RW]	[a] Pharmacor Metformin XR [CR]
			[B]5.34	23.10	19.21	[a] Diabex XR 500 [AL]	

metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1801T NP	1	5	..	16.69	18.14	[a] APX-Metformin [TY]	[a] Blooms The Chemist Metformin 850 mg [BG]
						[a] Diaformin 850 [AF]	[a] FORMET 850 [RF]
						[a] Glucobete 850 [ZS]	[a] Metformin Sandoz [SZ]
			[B]5.47	22.16	18.14	[a] Diabex 850 [AL]	

▪ METFORMIN

Restricted benefit

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

metformin hydrochloride 1 g tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14056T NP	2	5	..	*22.07	23.52	[a] APX-Metformin [TY]	[a] Blooms The Chemist Metformin 1000 mg [BG]
						[a] Diaformin 1000 [AF]	[a] Formet 1000 [RW]
						[a] Glucobete 1000 [ZS]	[a] Metformin GH [HQ]

						[a] Metformin Sandoz [SZ]	
			[B]9.78	*31.85	23.52	[a] Diabex 1000 [AL]	

metformin hydrochloride 1 g modified release tablet, 60

13847T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	[a] APO-Metformin XR 1000 [TX]	[a] Blooms the Chemist Metformin XR 1000 [IB]
						[a] Diaformin XR 1000 [AF]	[a] METEX XR [RF]
						[a] Pharmacor Metformin XR [CR]	
			[B]10.68	*32.75	23.52	[a] Diabex XR 1000 [AL]	

metformin hydrochloride 500 mg tablet, 100

13976N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.93	21.38	[a] APX-Metformin [TY]	[a] Blooms The Chemist Metformin 500 mg [BG]
						[a] Diaformin [AF]	[a] FORMET 500 [RF]
						[a] Glucobete 500 [ZS]	[a] Metformin GH [HQ]
						[a] Metformin Sandoz [SZ]	
			[B]10.94	*30.87	21.38	[a] Diabex [AL]	

metformin hydrochloride 500 mg modified release tablet, 120

13899M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	[a] APO-Metformin XR 500 [TX]	[a] Blooms the Chemist Metformin XR 500 [IB]
						[a] Metex XR [RW]	[a] Pharmacor Metformin XR [CR]
			[B]10.68	*32.75	23.52	[a] Diabex XR 500 [AL]	

metformin hydrochloride 850 mg tablet, 60

13952H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.93	21.38	[a] APX-Metformin [TY]	[a] Blooms The Chemist Metformin 850 mg [BG]
						[a] Diaformin 850 [AF]	[a] FORMET 850 [RF]
						[a] Glucobete 850 [ZS]	[a] Metformin Sandoz [SZ]
			[B]10.94	*30.87	21.38	[a] Diabex 850 [AL]	

Sulfonylureas

▪ GLIBENCLAMIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

glibenclamide 5 mg tablet, 100

2939Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	Daonil [SW]

▪ GLIBENCLAMIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

glibenclamide 5 mg tablet, 100

13868X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	Daonil [SW]

▪ GLICLAZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

gliclazide 30 mg modified release tablet, 100

8535F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.78	20.23	[a] APO-Gliclazide MR [TX]	[a] Gliclazide MR Viatris [AL]
						[a] Glyade MR [AF]	[a] Pharmacor Gliclazide MR [CR]

gliclazide 60 mg modified release tablet, 60

9302N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.67	19.12	[a] ARDIX GLICLAZIDE 60mg MR [XT]	[a] Gliclazide Lupin MR [GQ]
						[a] Pharmacor Gliclazide MR [CR]	
			[B]6.75	24.42	19.12	[a] Diamicron 60mg MR [SE]	

gliclazide 80 mg tablet, 100

2449X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.59	20.04	[a] APO-Gliclazide [TX]	[a] APX-Gliclazide [TY]
						[a] Glyade [AF]	[a] Nidem [RW]

▪ GLICLAZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

gliclazide 60 mg modified release tablet, 60

13922R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.89	23.34	[a] ARDIX GLICLAZIDE 60mg MR [XT] [a] Pharmacor Gliclazide MR [CR]	[a] Gliclazide Lupin MR [GQ]
		[B]13.50	*35.39	23.34	[a] Diamicron 60mg MR [SE]	

gliclazide 80 mg tablet, 100

13896J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*23.73	25.18	[a] APO-Gliclazide [TX] [a] Glyade [AF]	[a] APX-Gliclazide [TY] [a] Nidem [RW]

▪ GLIMEPIRIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

glimepiride 1 mg tablet, 30

8450R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]
		[B]2.21	18.38	17.62	[a] Amaryl [SW]	

glimepiride 2 mg tablet, 30

8451T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]

glimepiride 3 mg tablet, 30

8533D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.36	17.81	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]

glimepiride 4 mg tablet, 30

8452W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.90	18.35	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]

▪ GLIMEPIRIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

glimepiride 1 mg tablet, 30

13848W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]
		[B]4.42	*23.31	20.34	[a] Amaryl [SW]	

glimepiride 2 mg tablet, 30

13870B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]

glimepiride 3 mg tablet, 30

14020X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*19.27	20.72	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]

glimepiride 4 mg tablet, 30

14055R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.35	21.80	[a] ARX-GLIMEPIRIDE [XT] [a] Glimepiride Sandoz [SZ]	[a] Glimepiride APOTEX [GX]

▪ GLIPIZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

glipizide 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2440K NP	1	5	..	21.53	22.98	[a] Melizide [AF]	[a] Minidiab [PF]

▪ GLIPIZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

glipizide 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14019W NP	2	5	..	*29.61	31.06	[a] Melizide [AF]	[a] Minidiab [PF]

Combinations of oral blood glucose lowering drugs

▪ ALOGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10033C NP	1	5	..	53.38	31.60	Nesina Met 12.5/500 [TK]

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10032B NP	1	5	..	54.35	31.60	Nesina Met 12.5/850 [TK]

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10035E NP	1	5	..	54.74	31.60	Nesina Met 12.5/1000 [TK]

▪ ALOGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15288

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14062D NP	2	5	..	*93.31	31.60	Nesina Met 12.5/500 [TK]

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14061C NP	2	5	..	*95.25	31.60	Nesina Met 12.5/850 [TK]

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13989G NP	2	5	..	*96.03	31.60	Nesina Met 12.5/1000 [TK]

▪ DAPAGLIFLOZIN + METFORMIN

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15289

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10510E NP	1	5	..	59.01	31.60	Xigduo XR 5/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10515K NP	1	5	..	57.58	31.60	Xigduo XR 10/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10516L NP	1	5	..	56.81	31.60	Xigduo XR 10/500 [AP]

▪ DAPAGLIFLOZIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15267

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13851B NP	2	5	..	*104.57	31.60	Xigduo XR 5/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13875G NP	2	5	..	*101.71	31.60	Xigduo XR 10/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14028H NP	2	5	..	*100.17	31.60	Xigduo XR 10/500 [AP]

▪ EMPAGLIFLOZIN + LINAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15269

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11269D NP	1	5	..	83.01	31.60	Glyxambi [BY]

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11303X NP	1	5	..	83.01	31.60	Glyxambi [BY]

▪ EMPAGLIFLOZIN + LINAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15270

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13904T NP	2	5	..	*154.51	31.60	Glyxambi [BY]

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13958P NP	2	5	..	*154.51	31.60	Glyxambi [BY]

▪ EMPAGLIFLOZIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15289

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10626G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	63.08	31.60	Jardiamet 5 mg/500 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10627H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	64.60	31.60	Jardiamet 5 mg/1000 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10633P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	63.08	31.60	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10677Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	64.60	31.60	Jardiamet 12.5 mg/1000 mg [BY]

▪ EMPAGLIFLOZIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15267

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

14029J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*112.71	31.60	Jardiamet 5 mg/500 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

13852C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*115.85	31.60	Jardiamet 5 mg/1000 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

13903R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*112.71	31.60	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13987E NP	2	5	..	*115.85	31.60	Jardiamet 12.5 mg/1000 mg [BY]

▪ LINAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10038H NP	1	5	..	63.59	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10045Q NP	1	5	..	64.66	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10044P NP	1	5	..	65.10	31.60	Trajentamet [BY]

▪ LINAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15288

Diabetes mellitus type 2

Clinical criteria:

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

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13959Q NP	2	5	..	*113.73	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14065G NP	2	5	..	*115.99	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13879L NP	2	5	..	*116.91	31.60	Trajentamet [BY]

▪ SAXAGLIPTIN + DAPAGLIFLOZIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15269

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11286B NP	1	5	..	76.72	31.60	Qtern 5/10 [AP]

▪ SAXAGLIPTIN + DAPAGLIFLOZIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15270

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

13855F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*141.31	31.60	Qtern 5/10 [AP]

NP

▪ SAXAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

10055F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	59.50	31.60	Kombiglyze XR 5/500 [AP]

NP

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

10051B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.25	31.60	Kombiglyze XR 5/1000 [AP]

NP

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

10048W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	61.66	31.60	Kombiglyze XR 2.5/1000 [AP]

NP

▪ SAXAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15288

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

14030K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*105.55	31.60	Kombiglyze XR 5/500 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

13876H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*107.05	31.60	Kombiglyze XR 5/1000 [AP]

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

13880M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*109.87	31.60	Kombiglyze XR 2.5/1000 [AP]

▪ SITAGLIPTIN + METFORMIN

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

9451K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	40.26	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/1000 SUN [RA]
					[a] Sitagliptin/Metformin Mylan 50/1000 [AF]	[a] Sitagliptin/Metformin Sandoz [SZ]
					[a] Velmetia [XT]	

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

9449H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	39.22	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/500 SUN [RA]
					[a] Sitagliptin/Metformin Mylan 50/500 [AF]	[a] Sitagliptin/Metformin Sandoz [SZ]

[a] Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9450J NP	1	5	..	39.96	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/850 SUN [RA]
						[a] Sitagliptin/Metformin Mylan 50/850 [AF]	[a] Sitagliptin/Metformin Sandoz [SZ]
						[a] Velmetia [XT]	

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10089B NP	1	5	..	45.16	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10090C NP	1	5	..	46.22	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

▪ SITAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15288

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14035Q NP	2	5	..	*67.07	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/1000 SUN [RA]
						[a] Sitagliptin/Metformin Mylan 50/1000 [AF]	[a] Sitagliptin/Metformin Sandoz [SZ]
						[a] Velmetia [XT]	

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13994M NP	2	5	..	*64.99	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/500 SUN [RA]
						[a] Sitagliptin/Metformin Mylan 50/500 [AF]	[a] Sitagliptin/Metformin Sandoz [SZ]
						[a] Velmetia [XT]	

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14064F NP	2	5	..	*66.47	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/850 SUN [RA]
						[a] Sitagliptin/Metformin Mylan 50/850 [AF]	[a] Sitagliptin/Metformin Sandoz [SZ]
						[a] Velmetia [XT]	

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14031L NP	2	5	..	*76.87	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13990H NP	2	5	..	*78.99	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

▪ VILDAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5476F NP	1	5	..	51.98	31.60	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5474D NP	1	5	..	50.67	31.60	Galvumet 50/500 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5475E NP	1	5	..	51.52	31.60	Galvumet 50/850 [NV]

▪ VILDAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15288

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14032M NP	2	5	..	*90.51	31.60	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13877J NP	2	5	..	*87.89	31.60	Galvumet 50/500 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13991J NP	2	5	..	*89.59	31.60	Galvumet 50/850 [NV]

Alpha glucosidase inhibitors

▪ ACARBOSE

acarbose 100 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8189B NP	1	5	..	33.99	31.60	[a] Acarbose Viatris [AL]	[a] GLYBOSAY [RW]

acarbose 50 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8188Y NP	1	5	..	27.95	29.40	[a] Acarbose Mylan [AF] [a] GLYBOSAY [RW]	[a] Acarbose Viatris [AL]

▪ ACARBOSE

Restricted benefit

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

acarbose 100 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13869Y NP	2	5	..	*54.53	31.60	[a] Acarbose Viatris [AL]	[a] GLYBOSAY [RW]

acarbose 50 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13955L NP	2	5	..	*42.45	31.60	[a] Acarbose Mylan [AF] [a] GLYBOSAY [RW]	[a] Acarbose Viatris [AL]

Thiazolidinediones

▪ PIOGLITAZONE

Restricted benefit

Diabetes mellitus type 2

pioglitazone 15 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8694N NP	1	5	..	20.10	21.55	[a] Acpio 15 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8695P NP	1	5	..	23.69	25.14	[a] Acpio 30 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 45 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8696Q NP	1	5	..	26.76	28.21	[a] Acpio 45 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

▪ PIOGLITAZONE

Restricted benefit

Diabetes mellitus type 2

Clinical criteria:

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

pioglitazone 15 mg tablet, 28

13898L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*26.75	28.20	[a] Acpio 15 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 30 mg tablet, 28

13921Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*33.93	31.60	[a] Acpio 30 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 45 mg tablet, 28

14057W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*40.07	31.60	[a] Acpio 45 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

Dipeptidyl peptidase 4 (DPP-4) inhibitors

▪ ALOGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15261

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 6.25 mg tablet, 28

2944Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.95	31.60	Nesina [TK]

alogliptin 12.5 mg tablet, 28

2933J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.95	31.60	Nesina [TK]

alogliptin 25 mg tablet, 28

2986E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.95	31.60	Nesina [TK]

▪ ALOGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate

responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15287

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 6.25 mg tablet, 28

13897K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*90.45	31.60	Nesina [TK]

alogliptin 12.5 mg tablet, 28

13977P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*90.45	31.60	Nesina [TK]

alogliptin 25 mg tablet, 28

13953J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*90.45	31.60	Nesina [TK]

▪ LINAGLIPTIN

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15261

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3387G NP	1	5	..	59.55	31.60	Trajenta [BY]

▪ LINAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15287

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13954K NP	2	5	..	*105.65	31.60	Trajenta [BY]

▪ SAXAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15261

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8983T NP	1	5	..	56.48	31.60	Onglyza [AP]

saxagliptin 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10128C NP	1	5	..	56.48	31.60	Onglyza [AP]

▪ SAXAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15287

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13923T NP	2	5	..	*99.51	31.60	Onglyza [AP]

saxagliptin 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13895H NP	2	5	..	*99.51	31.60	Onglyza [AP]

▪ SITAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15261

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9182G NP	1	5	..	38.11	31.60	[a] Januvia [XW] [a] Sitagliptin Mylan [AF] [a] Sitagliptin SUN [RA] [a] Xelevia [XT]	[a] Sitagliptin Lupin [GQ] [a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]

sitagliptin 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9180E NP	1	5	..	38.11	31.60	[a] Januvia [XW] [a] Sitagliptin Mylan [AF] [a] Sitagliptin SUN [RA] [a] Xelevia [XT]	[a] Sitagliptin Lupin [GQ] [a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]

sitagliptin 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9181F NP	1	5	..	38.11	31.60	[a] Januvia [XW] [a] Sitagliptin Mylan [AF] [a] Sitagliptin SUN [RA] [a] Xelevia [XT]	[a] Sitagliptin Lupin [GQ] [a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]

▪ SITAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15287

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13871C NP	2	5	..	*62.77	31.60	[a] Januvia [XW] [a] Sitagliptin Mylan [AF] [a] Sitagliptin SUN [RA] [a] Xelevia [XT]	[a] Sitagliptin Lupin [GQ] [a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]

sitagliptin 25 mg tablet, 28

14021Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*62.77	31.60	[a] Januvia [XW] [a] Sitagliptin Mylan [AF] [a] Sitagliptin SUN [RA] [a] Xelevia [XT]	[a] Sitagliptin Lupin [GQ] [a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]

sitagliptin 50 mg tablet, 28

14058X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*62.77	31.60	[a] Januvia [XW] [a] Sitagliptin Mylan [AF] [a] Sitagliptin SUN [RA] [a] Xelevia [XT]	[a] Sitagliptin Lupin [GQ] [a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]

▪ VILDAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15261

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg tablet, 60

3415R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	50.59	31.60	Galvus [NV]

▪ VILDAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15287

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13846R NP	2	5	..	*87.73	31.60	Galvus [NV]

Glucagon-like peptide-1 (GLP-1) analogues

▪ DULAGLUTIDE

Note Special Pricing Arrangements apply.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

Authority required (STREAMLINED)

15263

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14150R NP	1	5	..	134.27	31.60	Trulicity [LY]

▪ DULAGLUTIDE

Note Special Pricing Arrangements apply.

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

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

Authority required

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11364D NP	1	5	..	134.27	31.60	Trulicity [LY]

▪ SEMAGLUTIDE

Note Special Pricing Arrangements apply.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

Authority required (STREAMLINED)

15263

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14149Q NP	‡1	5	..	134.27	31.60	Ozempic [NO]

semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14163K NP	‡1	5	..	134.27	31.60	Ozempic [NO]

▪ SEMAGLUTIDE

Note Special Pricing Arrangements apply.

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

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

Authority required

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12080T NP	‡1	5	..	134.27	31.60	Ozempic [NO]

semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12075M NP	‡1	5	..	134.27	31.60	Ozempic [NO]

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

13230

Chronic kidney disease

Clinical criteria:

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m^2 inclusive prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

dapagliflozin 10 mg tablet, 28

13106T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	56.05	31.60	Forxiga [AP]

NP

▪ DAPAGLIFLOZIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15311

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

dapagliflozin 10 mg tablet, 28

10011X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	56.05	31.60	Forxiga [AP]

NP

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

15047

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12823X NP	1	5	..	56.05	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15265

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

dapagliflozin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13844P NP	2	5	..	*98.65	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

15051

Chronic heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**

- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14054Q NP	2	5	..	*98.65	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14471

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14073Q NP	1	5	..	56.05	31.60	Forxiga [AP]

▪ EMPAGLIFLOZIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15311

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10206E NP	1	5	..	61.24	31.60	Jardiance [BY]

empagliflozin 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10202Y NP	1	5	..	61.48	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

15047

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12918X NP	1	5	..	61.24	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

13230

Chronic kidney disease

Clinical criteria:

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m^2 inclusive prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14092Q NP	1	5	..	61.24	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15265

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13845Q NP	2	5	..	*109.03	31.60	Jardiance [BY]

empagliflozin 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13920P NP	2	5	..	*109.51	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

15051

Chronic heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**

- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14018T NP	2	5	..	*109.03	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14471

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13695T NP	1	5	..	61.24	31.60	Jardiance [BY]

▪ VITAMINS

VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

Vitamin D and analogues

▪ CALCITRIOL

Authority required (STREAMLINED)

5401

Hypocalcaemia

Clinical criteria:

- The condition must be due to renal disease.

Authority required (STREAMLINED)

5255

Hypoparathyroidism

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5402

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2502Q NP	1	3	..	29.58	31.03	[a] APO-Calcitriol [TX] [a] CALITROL [XT] [a] Sical [AF]	[a] Calciprox [ZS] [a] Kosteo [RW]

[B]2.29	31.87	31.03	[a] Rocaltrol [IX]	

▪ CALCITRIOL

Authority required (STREAMLINED)

14322

Hypocalcaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

Authority required (STREAMLINED)

14287

Hypoparathyroidism

Clinical criteria:

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

Authority required (STREAMLINED)

14231

Hypophosphataemic rickets

Clinical criteria:

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

Authority required (STREAMLINED)

14296

Vitamin D-resistant rickets

Clinical criteria:

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

Authority required (STREAMLINED)

14259

Established osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

13457G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*45.71	31.60	[a] APO-Calcitriol [TX]	[a] Calciprox [ZS]
					[a] CALITROL [XT]	[a] Kosteo [RW]
					[a] Sical [AF]	
		[B]4.58	*50.29	31.60	[a] Rocaltrol [IX]	

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

▪ THIAMINE

Authority required (STREAMLINED)

5139

Thiamine deficiency

Clinical criteria:

- The treatment must be for prophylaxis.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

thiamine hydrochloride 100 mg tablet, 100

1070H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17.35	18.80	Betavit [PP]

▪ THIAMINE

Authority required (STREAMLINED)

14319

Thiamine deficiency

Clinical criteria:

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

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

thiamine hydrochloride 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13354W NP	2	2	..	*21.25	22.70	Betavit [PP]

MINERAL SUPPLEMENTS

CALCIUM

Calcium

CALCIUM

Authority required (STREAMLINED)

4586

Hyperphosphataemia

Clinical criteria:

- The condition must be associated with chronic renal failure.

calcium carbonate 1.5 g (calcium 600 mg) tablet, 240

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3117C NP	1	1	..	22.13	23.58	Calci-Tab 600 [AE]

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11726E NP	2	1	..	*29.55	31.00	Cal-500 [PP]

CALCIUM

Authority required (STREAMLINED)

14228

Hyperphosphataemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be associated with chronic renal failure.

calcium carbonate 1.5 g (calcium 600 mg) tablet, 240

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13547B NP	2	1	..	*30.81	31.60	Calci-Tab 600 [AE]

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13485R	4	1	..	*45.63	31.60	Cal-500 [PP]

POTASSIUM

Potassium

POTASSIUM CHLORIDE

potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1841X NP	1	1	..	25.29	26.74	Span-K [AS]

POTASSIUM CHLORIDE

Restricted benefit

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

potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13357B NP	2	1	..	*37.13	31.60	Span-K [AS]

▪ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60

3012M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	25.82	27.27	Chlorvescent [AS]

NP

▪ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

Restricted benefit

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

potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60

13486T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*38.19	31.60	Chlorvescent [AS]

NP

OTHER MINERAL SUPPLEMENTS

Magnesium

▪ MAGNESIUM

Authority required (STREAMLINED)

5506

Hypomagnesaemia

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)

5466

Chronic renal disease

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

magnesium 37.4 mg tablet, 50

5146W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.19	20.64	MagMin (PBS) [BB]	Mag-Sup [PP]

NP

▪ OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Amino acids and derivatives

▪ BETAINE

Authority required

Homocystinuria

Clinical criteria:

- The treatment must be as adjunctive therapy to current standard care, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

betaine 1 g/g powder for oral liquid, 180 g

10119N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	549.21	31.60	Cystadane [RJ]

Various alimentary tract and metabolism products

▪ SAPROPTERIN

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

Authority required

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11970B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4247.60	31.60	Kuvan [IO]

▪ SAPROPTERIN

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

Authority required

Hyperphenylalaninaemia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

sapropterin dihydrochloride 100 mg soluble tablet, 30

10087X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*5064.57	31.60	Kuvan [IO]

▪ SAPROPTERIN

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

Note Special Pricing Arrangements apply.

Authority required

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

Treatment criteria:

- Must be treated by a metabolic physician.

Clinical criteria:

- Patient must be untreated with this drug; OR
- Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; OR
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; OR
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

Dietary phenylalanine intake must be maintained at a constant level.

Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11971C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	4247.60	31.60	Kuvan [IO]

sapropterin dihydrochloride 100 mg soluble tablet, 30

11676M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	875.78	31.60	Kuvan [IO]

▪ SAPROPTERIN

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

Note Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

Authority required

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a metabolic physician.

Clinical criteria:

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11973E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	4247.60	31.60	Kuvan [IO]

▪ SAPROPTERIN

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

Note Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

Authority required

Hyperphenylalaninaemia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a metabolic physician.

Clinical criteria:

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

sapropterin dihydrochloride 100 mg soluble tablet, 30

10086W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	..	..	*5064.57	31.60	Kuvan [IO]

▪ SAPROPTERIN

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

Note Special Pricing Arrangements apply.

Authority required

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.

Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.

Dietary phenylalanine intake must be maintained at a constant level.

Authority required

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Subsequent continuing

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11983Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4247.60	31.60	Kuvan [IO]

saropterin dihydrochloride 100 mg soluble tablet, 30

11691H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*5064.57	31.60	Kuvan [IO]

▪ SAPROPTERIN

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

Note Request an appropriate maximum quantity based on testing response to treatment for 7 days, with the number of packs being a whole number, based on dosing no greater than 20 mg/kg per day. Combinations of the sachets and tablets are permitted to reduce high tablet burden.

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

Note Special Pricing Arrangements apply.

Authority required

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

Clinical criteria:

- The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase: First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU), **AND**
- Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels.

Treatment criteria:

- Must be treated by a metabolic physician, **AND**
- Patient must be undergoing treatment with this drug for the first time, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously).

Population criteria:

- Patient must be one of: (i) planning conception, (ii) pregnant.

saropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

12570N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	4247.60	31.60	Kuvan [IO]

saropterin dihydrochloride 100 mg soluble tablet, 30

12579C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	875.78	31.60	Kuvan [IO]

▪ SAPROPTERIN

Note Special Pricing Arrangements apply.

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

Note Request an appropriate maximum quantity (with the number of packs being a whole number) to provide approximately 30 days treatment duration per dispensing, based on dosing no greater than 20 mg/kg per day.

Authority required

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Pre-conception through to when pregnancy first becomes known

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, following completion of this authority application, for more than 13 cumulative months (assuming 1 month consists of 30 days), **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

Population criteria:

- Patient must be actively trying to conceive.

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

Note This PBS listing intends to subsidise up to 13 cumulative months (assuming 1 month consists of 30 days) of treatment during the pre-conception phase per known pregnancy. The time taken to conceive can vary for each patient, but where this treatment phase of 'pre-conception through to when pregnancy becomes first known' exceeds a cumulative 13 months, continued treatment beyond this time up to the point of conception, is not PBS subsidised.
13 cumulative months comprises of the time taken to achieve desired phenylalanine level control and the time taken for

pregnancy to become known (e.g. If it takes 3 months to reach desired phenylalanine level control, 10 months of PBS-subsidised treatment remain in which to achieve pregnancy; if it takes only 1 month to reach desired phenylalanine level control, 12 months of PBS-subsidised treatment remain in which to achieve pregnancy)

Authority required

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Existing pregnancy to birth

Population criteria:

- Patient must be pregnant.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing further treatment with this drug as a PBS benefit, post-partum in the absence of actively trying to conceive a subsequent child/a known subsequent pregnancy, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

Note Request an appropriate number of repeats (whole number) relative to the expected birth date such that treatment is not continued post-partum by a whole prescription quantity. If the expected birth date is within the next 30 days at the time of the authority application, do not request repeats.

Note This PBS listing intends to subsidise treatment only whilst the patient is pregnant. Treatment is to be discontinued upon birth under this listing. Whilst a patient may benefit from continued treatment post-partum, continued treatment with this drug post-partum is not PBS subsidised in the absence of actively trying to conceive again/a known subsequent pregnancy.

sapropterin dihydrochloride 100 mg soluble tablet, 30

12569M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	875.78	31.60	Kuvan [IO]

▪ SODIUM PHENYLBUTYRATE

Authority required (STREAMLINED)

9993

Urea cycle disorders

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone.

An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m^2/day in patients weighing more than 20 kg.

Authority required (STREAMLINED)

9919

Urea cycle disorders

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m^2/day in patients weighing more than 20 kg.

sodium phenylbutyrate 483 mg/g granules, 174 g

11865L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*1640.31	31.60	Pheburane [OH]

▪ TRIENTINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

Authority required

Chelation of elevated copper levels

Clinical criteria:

- Patient must have a diagnosis of Wilson disease, **AND**
- Patient must be intolerant to penicillamine.

Treatment criteria:

- Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type: (i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber; OR
- Must be treated by a medical practitioner (of any type), where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types; OR
- Must be treated by a nurse practitioner where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types.

Prior to seeking the initial authority approval, establish evidence of excess copper levels based on at least one of: (i) clinical symptoms, (ii) measured serum copper levels, (iii) measured urinary copper levels.

Document what these findings were in the patient's medical records. Do not supply them in this authority application.

Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine:

Side effects of penicillamine occurring soon after initiation (within first few weeks/months):

(i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea.

Side effects of penicillamine developing later:

(i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.

At the time of the first authority application for this drug, document the details (date of reaction, severity of reaction, dose of penicillamine, etc) of the penicillamine intolerance, if not already done, in the patient's medical records. Do not supply these details in this authority application.

trientine dihydrochloride 250 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13124R NP	2	5	..	*1797.81	31.60	[a] Trientine Dr. Reddy's [RZ]	[a] Trientine Waymade [IX]

BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Vitamin K antagonists

WARFARIN

Caution The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

warfarin sodium 1 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2843P NP	1	2	..	18.22	19.67	Coumadin [GO]	Marevan [GT]

warfarin sodium 2 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2209G NP	1	2	..	18.40	19.85	Coumadin [GO]

warfarin sodium 3 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2844Q NP	1	2	..	18.46	19.91	Marevan [GT]

warfarin sodium 5 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2211J NP	1	2	..	18.87	20.32	Coumadin [GO]	Marevan [GT]

Heparin group

ENOXAPARIN SODIUM

Restricted benefit

Haemodialysis

enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13688K NP	1	3	..	125.44	31.60	Exarane Forte [JU]

enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13717Y NP	1	3	..	154.69	31.60	Exarane Forte [JU]

ENOXAPARIN SODIUM

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Exarane and Exarane Forte is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information about Biosimilar Uptake Drivers can be found on the can be found on the PBS Biosimilars webpage (www.pbs.gov.au/info/general/biosimilars).

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

8264Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	111.95	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

8262W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	83.32	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

8263X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	87.73	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

8510X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	..	*94.17	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes

13710N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	125.44	31.60	[a] Clexane Forte Safety-Lock [AV]	[a] Exarane Forte [JU]

enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes

13729N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	154.69	31.60	[a] Clexane Forte Safety-Lock [AV]	[a] Exarane Forte [JU]

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

8558K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	..	*85.69	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

▪ ENOXAPARIN SODIUM

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Exarane and Exarane Forte is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information about Biosimilar Uptake Drivers can be found on the can be found on the PBS Biosimilars webpage (www.pbs.gov.au/info/general/biosimilars).

Restricted benefit

Haemodialysis

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

5435C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*215.29	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

8640R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*155.17	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

5434B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*164.43	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

8639Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*94.17	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

8716R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*85.69	31.60	[a] Clexane Safety-Lock [AV]	[a] Exarane [JU]

▪ HEPARIN

heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules

1466E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	44.26	31.60	DBL Heparin Sodium [PF]

Platelet aggregation inhibitors excl. heparin

▪ ASPIRIN

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 100 mg tablet, 112

8202Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	15.58	17.03	Spren 100 [OW]

▪ CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

clopidogrel 75 mg tablet, 28

8358X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.55	19.00	[a] Blooms Clopidogrel [BG]	[a] Clopidogrel Lupin [GQ]
					[a] Clopidogrel Sandoz Pharma [HX]	[a] Clopidogrel Winthrop [WA]
					[a] Iscover [AV]	[a] Piax [AF]
					[a] Plavicor 75 [CR]	

clopidogrel 75 mg tablet, 28

9354H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.55	19.00	[a] BTC Clopidogrel [JB]	[a] Clovix 75 [RW]
					[a] Plidogrel [RF]	

▪ CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

clopidogrel 75 mg tablet, 28

13365K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.65	23.10	[a] BTC Clopidogrel [JB]	[a] Clovix 75 [RW]
					[a] Plidogrel [RF]	

clopidogrel 75 mg tablet, 28

13399F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.65	23.10	[a] Blooms Clopidogrel [BG]	[a] Clopidogrel Lupin [GQ]
					[a] Clopidogrel Sandoz Pharma [HX]	[a] Clopidogrel Winthrop [WA]
					[a] Iscover [AV]	[a] Piax [AF]
					[a] Plavicor 75 [CR]	

▪ CLOPIDOGREL + ASPIRIN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

clopidogrel 75 mg + aspirin 100 mg tablet, 30

9296G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.84	19.29	[a] APX-Clopidogrel/Aspirin 75/100 [TY]	[a] Clopidogrel Winthrop plus aspirin [WA]
					[a] DuoCover [AV]	[a] DuoPlidogrel [GZ]
					[a] Piax Plus Aspirin [AF]	

▪ CLOPIDOGREL + ASPIRIN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

clopidogrel 75 mg + aspirin 100 mg tablet, 30

13427Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.23	23.68	[a] APX-Clopidogrel/Aspirin 75/100 [TY] [a] DuoCover [AV] [a] Piax Plus Aspirin [AF]	[a] Clopidogrel Winthrop plus aspirin [WA] [a] DuoPlidogrel [GZ]

▪ TICAGRELOR

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5746

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

- The treatment must be in combination with aspirin.

ticagrelor 90 mg tablet, 56

1418P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	131.28	31.60	Brilinta [AP]

▪ TICAGRELOR

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14240

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with aspirin.

ticagrelor 90 mg tablet, 56

13524T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*254.09	31.60	Brilinta [AP]

▪ TIROFIBAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5782

High risk of unstable angina

Clinical criteria:

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

Authority required (STREAMLINED)

5809

High risk of unstable angina

Clinical criteria:

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

Authority required (STREAMLINED)

5691

Non-Q-wave myocardial infarction

tirofiban 12.5 mg/50 mL injection, 50 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8350L NP	1	2	..	183.55	31.60	[a] Aggrastat [AS]	[a] Tirofiban Juno [JU]

Enzymes

▪ TENECTEPLASE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Acute myocardial infarction
Clinical criteria:
- The treatment must be administrated within 12 hours of onset of attack.

tenecteplase 40 mg injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8526R NP	1	..	..	1875.17	31.60	Metalyse [BY]

▪ TENECTEPLASE

Note Pharmaceutical benefits that have the brand Metalyse 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack and pharmaceutical benefits that have the brand TNKase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack are equivalent for the purposes of substitution in the case of a shortage.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Acute myocardial infarction
Clinical criteria:
- The treatment must be administrated within 12 hours of onset of attack.

tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13128Y NP	1	..	..	5162.60	31.60	[a] TNKase (Canada) [QY]	[a] TNKase (Canada) Medsurge Healthcare Pty Ltd [DZ]

tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8527T NP	1	..	..	1971.24	31.60	[a] Metalyse [BY]

Direct thrombin inhibitors

▪ BIVALIRUDIN

Authority required (STREAMLINED)
4919
Coronary artery disease
Treatment criteria:
- Patient must be undergoing percutaneous coronary intervention.

bivalirudin 250 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8844L	1	..	..	475.72	31.60	[a] Bivalirudin APOTEX [TX]	[a] BIVALIRUDIN ARX [XT]

▪ DABIGATRAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)
4269
Prevention of stroke or systemic embolism
Clinical criteria:
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

dabigatran etexilate 110 mg capsule, 60

2753X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	53.39	31.60	[a] ARX-Dabigatran [XT] [a] PHARMACOR DABIGATRAN [CR]	[a] Dabigatran Sandoz [SZ] [a] Pradaxa [BY]

dabigatran etexilate 150 mg capsule, 60

2769R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	53.11	31.60	[a] ARX-Dabigatran [XT] [a] PHARMACOR DABIGATRAN [CR]	[a] Dabigatran Sandoz [SZ] [a] Pradaxa [BY]

▪ DABIGATRAN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4402
Prevention of venous thromboembolism
Treatment criteria:
- Patient must be undergoing total hip replacement.

Clinical criteria:
- Patient must require up to 30 days supply to complete a course of treatment.

dabigatran etexilate 110 mg capsule, 60

9321N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	53.39	31.60	[a] ARX-Dabigatran [XT] [a] PHARMACOR DABIGATRAN [CR]	[a] Dabigatran Sandoz [SZ] [a] Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 60

9320M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	80.10	31.60	[a] ARX-Dabigatran [XT] [a] Pradaxa [BY]	[a] PHARMACOR DABIGATRAN [CR]

▪ DABIGATRAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
14308
Prevention of stroke or systemic embolism
Clinical criteria:
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

dabigatran etexilate 110 mg capsule, 60

13523R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*93.33	31.60	[a] ARX-Dabigatran [XT] [a] PHARMACOR DABIGATRAN [CR]	[a] Dabigatran Sandoz [SZ] [a] Pradaxa [BY]

dabigatran etexilate 150 mg capsule, 60

13489Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*92.77	31.60	[a] ARX-Dabigatran [XT] [a] PHARMACOR DABIGATRAN [CR]	[a] Dabigatran Sandoz [SZ] [a] Pradaxa [BY]

▪ DABIGATRAN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4369
Prevention of venous thromboembolism
Treatment criteria:
- Patient must be undergoing total hip replacement.

Clinical criteria:
- Patient must require up to 20 days supply to complete a course of treatment.

dabigatran etexilate 75 mg capsule, 10

9318K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*35.69	31.60	Pradaxa [BY]

dabigatran etexilate 110 mg capsule, 10

9319L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*26.79	28.24	Pradaxa [BY]

▪ DABIGATRAN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4381
Prevention of venous thromboembolism
Treatment criteria:
- Patient must be undergoing total knee replacement.

Clinical criteria:
- Patient must require up to 10 days of therapy.

dabigatran etexilate 75 mg capsule, 10

9322P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*35.69	31.60	Pradaxa [BY]

dabigatran etexilate 110 mg capsule, 10

9323Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*26.79	28.24	Pradaxa [BY]

Direct factor Xa inhibitors

▪ APIXABAN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4402
Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 30 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 60

5061J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	91.20	31.60	Eliquis [BQ]

NP

▪ APIXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4098

Deep vein thrombosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

5098

Pulmonary embolism

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 28

10414D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	49.74	31.60	Eliquis [BQ]

NP

▪ APIXABAN

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

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

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4382

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 15 days of therapy.

Authority required (STREAMLINED)

4409

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 15 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 30

5054B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	52.33	31.60	Eliquis [BQ]

NP

▪ APIXABAN

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

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

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4381

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 10 days of therapy.

Authority required (STREAMLINED)

4359

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 10 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 20

5500L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	39.37	31.60	Eliquis [BQ]

NP

▪ APIXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4132

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a history of venous thromboembolism.

apixaban 2.5 mg tablet, 60

2744K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	91.20	31.60	Eliquis [BQ]

NP

▪ APIXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

14308

Prevention of stroke or systemic embolism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14300

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

apixaban 2.5 mg tablet, 60

13464P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*171.71	31.60	Eliquis [BQ]

▪ APIXABAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4099

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

5083

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 60

2735Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	91.20	31.60	Eliquis [BQ]

▪ APIXABAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

14308

Prevention of stroke or systemic embolism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14264

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

14302

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 60

13525W

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*171.71	31.60	Eliquis [BQ]

▪ RIVAROXABAN

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

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

Authority required (STREAMLINED)

11013

Chronic stable atherosclerotic disease

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy, **AND**
- Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; OR
- Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent, **AND**
- Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; OR
- Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%, **AND**
- The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication, **AND**
- Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of

fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

rivaroxaban 2.5 mg tablet, 60

12197Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.59	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4132

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a history of venous thromboembolism.

rivaroxaban 10 mg tablet, 30

11633G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	66.83	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

rivaroxaban 15 mg tablet, 28

2691P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.46	31.60	Xarelto [BN]

▪ RIVAROXABAN

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

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

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 30 days supply to complete a course of treatment.

rivaroxaban 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9467G NP	1	..	..	66.83	31.60	Xarelto [BN]

rivaroxaban 10 mg tablet, 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9466F NP	1	1	..	40.15	31.60	Xarelto [BN]

▪ RIVAROXABAN

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

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

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4382

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 15 days of therapy.

rivaroxaban 10 mg tablet, 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9469J NP	1	..	..	40.15	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

14301

Prevention of stroke or systemic embolism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

rivaroxaban 15 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13463N NP	2	5	..	*107.47	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

14300

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

rivaroxaban 10 mg tablet, 30

13521P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*120.53	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Note Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

Authority required (STREAMLINED)

10992

Chronic stable atherosclerotic disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

rivaroxaban 2.5 mg tablet, 60

12192Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.59	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4098

Deep vein thrombosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4260

Pulmonary embolism

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

rivaroxaban 15 mg tablet, 42

2160Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	83.96	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Note Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

Authority required (STREAMLINED)

14298

Chronic stable atherosclerotic disease

Treatment Phase: Continuing treatment

Clinical criteria:

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

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

rivaroxaban 2.5 mg tablet, 60

13366L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*107.73	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

4099

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4132

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a history of venous thromboembolism.

Authority required (STREAMLINED)

4268

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

rivaroxaban 20 mg tablet, 28

2268J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	59.88	31.60	Xarelto [BN]

▪ RIVAROXABAN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

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

Authority required (STREAMLINED)

14264

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

14300

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

Authority required (STREAMLINED)

14318

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

Authority required (STREAMLINED)

14301

Prevention of stroke or systemic embolism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

rivaroxaban 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13462M NP	2	5	..	*106.31	31.60	Xarelto [BN]

Other antithrombotic agents

▪ FONDAPARINUX

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

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

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5781

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing major hip surgery.

Authority required (STREAMLINED)

5808

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

fondaparinux sodium 2.5 mg/0.5 mL injection, 2 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8775W NP	3.5	..	..	*117.89	31.60	Arixtra [AS]

▪ ANTIHEMORRHAGICS

ANTIFIBRINOLYTICS

Amino acids

▪ TRANEXAMIC ACID

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

tranexamic acid 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2180R NP	1	2	..	39.09	31.60	[a] APO-Tranexamic Acid [TX]	[a] Tranexamic Acid Lupin [GQ]
			[B]8.31	47.40	31.60	[a] Cyklokapron [PF]	

ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

FERROUS FUMARATE

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8985X NP	1	1	..	19.79	21.24	Ferro-tab [AE]

FERROUS SULFATE

ferrous sulfate heptahydrate 30 mg/mL (iron 6 mg/mL) oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8815Y NP	‡1	2	..	22.59	24.04	Ferro-Liquid [AE]

Iron, parenteral preparations

FERRIC CARBOXYMALTOSE

Note Special Pricing Arrangements apply.

iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11702X NP	1	1	..	300.18	31.60	Ferinject [CS]

iron (as ferric carboxymaltose) 500 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10104T NP	2	1	..	*300.19	31.60	Ferinject [CS]

FERRIC DERISOMALTOSE

Note Special Pricing Arrangements apply.

iron (as ferric derisomaltose) 1 g/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12049E NP	1	1	..	285.60	31.60	Monofer [FK]

iron (as ferric derisomaltose) 500 mg/5 mL injection, 5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11615H NP	3	..	..	*424.17	31.60	Monofer [FK]

IRON POLYMALTOSE

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2593L NP	1	..	..	33.89	31.60	Ferrosig [SI]

IRON POLYMALTOSE

Authority required (STREAMLINED)

4302

Iron deficiency anaemia

Treatment criteria:

- Patient must be undergoing chronic haemodialysis.

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2805P NP	1	5	..	33.89	31.60	Ferrosig [SI]

▪ IRON SUCROSE

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

10229J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	39.53	31.60	Venofer [VL]

NP

▪ IRON SUCROSE

Authority required (STREAMLINED)

4302

Iron deficiency anaemia

Treatment criteria:

- Patient must be undergoing chronic haemodialysis.

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

8807M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	39.53	31.60	Venofer [VL]

NP

Iron in combination with folic acid

▪ FERROUS FUMARATE + FOLIC ACID

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60

9011G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	20.76	22.21	Ferro-f-tab [AE]

NP

VITAMIN B12 AND FOLIC ACID

Vitamin B12 (cyanocobalamin and analogues)

▪ HYDROXOCOBALAMIN

Note One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B_{12} deficiencies.

Note Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

Restricted benefit

Pernicious anaemia

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Anaemias associated with vitamin B12 deficiency

Clinical criteria:

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

2162T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.84	19.29	[a] Cobal-B12 [JU]	[a] Vita-B12 [GH]

NP

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

9048F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.84	19.29	[a] Hydroxo-B12 [AS]	[a] Neo-B12 [PF]

NP

Folic acid and derivatives

▪ FOLIC ACID

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

folic acid 500 microgram tablet, 100

2958Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*17.67	19.12	[a] Foltabs 500 [PP]	[a] Megafol 0.5 [AF]

NP

▪ FOLIC ACID

Note The 5 mg strength tablet should be used in malabsorption states only.

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

folic acid 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1437P NP	2	1	..	*19.75	21.20	Megafol 5 [AF]

▪ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

BLOOD AND RELATED PRODUCTS

Blood substitutes and plasma protein fractions

▪ HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE

HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9487H NP	3	..	..	*43.23	31.60	Voluven 6% [PK]

▪ OTHER HEMATOLOGICAL AGENTS

OTHER HEMATOLOGICAL AGENTS

Drugs used in hereditary angioedema

▪ ICATIBANT

Note Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

Clinical criteria:

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Increased maximum quantities will be limited to 12 injections per authority prescription.

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Increased maximum quantities will be limited to 12 injections per authority prescription.

icatibant 30 mg/3 mL injection, 3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1976B	1	1	..	852.10	31.60	[a] Cipla Icatibant [LR] [a] Icatibant Lupin [GQ]	[a] Fyzant [JU]

▪ LANADELUMAB

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

Note Special Pricing Arrangements apply.

Authority required

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)

Clinical criteria:

- Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug, **AND**
- Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application, **AND**
- The treatment must not be used in combination with a C1-esterase inhibitor concentrate.

Treatment criteria:

- Must be treated by a clinical immunologist or a specialist allergist.

Population criteria:

- Patient must be aged 12 years or older.

For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate

The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)

Clinical criteria:

- Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving lanadelumab, **AND**
- The treatment must not be used in combination with a C1-esterase inhibitor concentrate.

Treatment criteria:

- Must be treated by a clinical immunologist or a specialist allergist.

Population criteria:

- Patient must be aged 12 years or older.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Continuing preventative treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be PBS-subsidised in combination with a C1-esterase inhibitor concentrate.

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be aged 12 years or older.

Patients who have successfully transitioned to a lower dosing frequency should be reviewed every 6 months to ensure they continue to demonstrate a sustained response

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

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

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lanadelumab 300 mg/2 mL injection, 2 mL syringe

12790E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18602.70	31.60	Takhzyro [TK]

CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

CARDIAC GLYCOSIDES

Digitalis glycosides

DIGOXIN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

digoxin 50 microgram/mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3164M NP	2	3	..	*43.67	31.60	Lanoxin [AS]

digoxin 250 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1322N NP	1	1	..	17.37	18.82	[a] Sigmaxin [LN]
			[B]2.41	19.78	18.82	[a] Lanoxin [AS]

digoxin 62.5 microgram tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2605D NP	1	1	..	17.37	18.82	[a] Sigmaxin-PG [LN]
			[B]2.41	19.78	18.82	[a] Lanoxin-PG [AS]

ANTIARRHYTHMICS, CLASS I AND III

Antiarrhythmics, class Ia

DISOPYRAMIDE

Note Pharmaceutical benefits that have the form disopyramide 100 mg capsule in a pack size of 84 can be substituted for a pack size of 100 in the case of a shortage.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

disopyramide 100 mg capsule, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13280Y NP	1.19	5	..	*87.21	31.60	[a] Rythmodan (Canada) [OJ]

disopyramide 100 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2923W NP	1	5	..	25.93	27.38	[a] Rythmodan [PB]

Antiarrhythmics, class Ib

LIDOCAINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

lidocaine hydrochloride 10% (500 mg/5 mL) injection, 10 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2876J NP	1	..	..	35.56	31.60	Xylocard 500 [AS]

Antiarrhythmics, class Ic

FLECAINIDE

Caution Flecainide acetate should be avoided in patients with poor cardiac function.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Serious supra-ventricular cardiac arrhythmias
Restricted benefit
Serious ventricular cardiac arrhythmias
Clinical criteria:

- The treatment must be initiated in a hospital.

flecainide acetate 100 mg tablet, 60

1090J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	33.37	31.60	[a] APO-Flecainide [TX] [a] Flecatab [AF]	[a] Flecainide Sandoz [SZ]
		[B]7.10	40.47	31.60	[a] Tambocor [IL]	

flecainide acetate 50 mg tablet, 60

1088G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	29.52	30.97	[a] APO-Flecainide [TX] [a] Flecatab [AF]	[a] Flecainide Sandoz [SZ]
		[B]6.56	36.08	30.97	[a] Tambocor [IL]	

Antiarrhythmics, class III

▪ AMIODARONE

Note This drug has been reported to cause frequent and potentially serious toxicity.

Note Regular monitoring of hepatic and thyroid function is recommended.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe cardiac arrhythmias

amiodarone hydrochloride 100 mg tablet, 30

2344J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.87	19.32	[a] Aratac 100 [AF]	[a] Cordarone X 100 [SW]

amiodarone hydrochloride 200 mg tablet, 30

2343H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.60	20.05	[a] Amdarone [XT] [a] APO-Amiodarone [TX] [a] Cordarone X 200 [SW]	[a] Amiodarone Sandoz [SZ] [a] Aratac 200 [AF]

▪ SOTALOL

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe cardiac arrhythmias

sotalol hydrochloride 160 mg tablet, 60

2043M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.37	21.82	[a] APX-Sotalol [TY] [a] Solavert [RF]	[a] Cardol [AF] [a] Sotalol Sandoz [SZ]
		[B]4.99	25.36	21.82	[a] Sotacor [RW]	

sotalol hydrochloride 80 mg tablet, 60

8398B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.36	18.81	[a] APX-Sotalol [TY] [a] Solavert [RF]	[a] Cardol [AF] [a] Sotalol Sandoz [SZ]
		[B]4.58	21.94	18.81	[a] Sotacor [RW]	

CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

Adrenergic and dopaminergic agents

▪ ADRENALINE (EPINEPHRINE)

Note Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

1016L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

5004J DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

▪ ADRENALINE (EPINEPHRINE)

Caution Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

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

Note No applications for repeats will be authorised.

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

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug.

adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8697R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*160.17	31.60	[a] Adrenaline Jr Viatris [AF] [a] EpiPen Jr. [AL]	[a] Anapen Junior 150 [XT]

adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

8698T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*160.17	31.60	[a] Adrenaline Viatris [AF] [a] EpiPen [AL]	[a] Anapen 300 [XT]

adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device

12655C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*160.17	31.60	Anapen 500 [XT]

VASODILATORS USED IN CARDIAC DISEASES

Organic nitrates

▪ GLYCERYL TRINITRATE

glyceryl trinitrate 15 mg/24 hours patch, 30

8119H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.61	31.60	Minitran 15 [IL]

glyceryl trinitrate 10 mg/24 hours patch, 30

1516T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	34.73	31.60	Transiderm-Nitro 50 [SZ]

glyceryl trinitrate 10 mg/24 hours patch, 30

8028M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	34.73	31.60	Minitran 10 [IL]

glyceryl trinitrate 5 mg/24 hours patch, 30

1515R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	29.68	31.13	Transiderm-Nitro 25 [SZ]

glyceryl trinitrate 5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8027L NP	1	5	..	29.68	31.13	Minitran 5 [IL]

▪ GLYCERYL TRINITRATE

Note The spray should not be inhaled.

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8171C NP	‡1	5	..	25.38	26.83	Nitrolingual Pumpspray [SW]

▪ GLYCERYL TRINITRATE

Restricted benefit

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

glyceryl trinitrate 10 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13580R NP	2	5	..	*56.01	31.60	Transiderm-Nitro 50 [SZ]

glyceryl trinitrate 5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13490B NP	2	5	..	*45.91	31.60	Transiderm-Nitro 25 [SZ]

▪ GLYCERYL TRINITRATE

Note The spray should not be inhaled.

Restricted benefit

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

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13549D NP	‡2	5	..	*37.31	31.60	Nitrolingual Pumpspray [SW]

▪ ISOSORBIDE DINITRATE

isosorbide dinitrate 5 mg sublingual tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2588F NP	2	2	..	*20.99	22.44	Isordil Sublingual [RW]

▪ ISOSORBIDE DINITRATE

Restricted benefit

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

isosorbide dinitrate 5 mg sublingual tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13491C NP	4	2	..	*28.51	29.96	Isordil Sublingual [RW]

▪ ISOSORBIDE MONONITRATE

isosorbide mononitrate 60 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1558B NP	1	5	..	17.22	18.67	[a] APO-Isosorbide Mononitrate [TX]	[a] Duride [AF]
						[a] ISOBIDE MR [RF]	
			[B]3.38	20.60	18.67	[a] Imdur Durule [IX]	

isosorbide mononitrate 120 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8273K NP	1	5	..	20.78	22.23	[a] Monodur 120 mg [IY]
			[B]3.37	24.15	22.23	[a] Imdur 120 mg [IX]

▪ ISOSORBIDE MONONITRATE

Restricted benefit

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

isosorbide mononitrate 60 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13461L NP	2	5	..	*20.99	22.44	[a] APO-Isosorbide Mononitrate [TX] [a] ISOBIDE MR [RF]	[a] Duride [AF]
			[B]6.76	*27.75	22.44	[a] Imdur Durule [IX]	

isosorbide mononitrate 120 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13611J NP	2	5	..	*28.11	29.56	[a] Monodur 120 mg [IY]
			[B]6.74	*34.85	29.56	[a] Imdur 120 mg [IX]

Other vasodilators used in cardiac diseases

▪ NICORANDIL

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

nicorandil 10 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8228C NP	‡1	5	..	22.14	23.59	[a] APO-Nicorandil [TX]	[a] Ikotab [AF]

nicorandil 20 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8229D NP	‡1	5	..	25.55	27.00	[a] APO-Nicorandil [TX]	[a] Ikotab [AF]

▪ NICORANDIL

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

nicorandil 10 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13550E NP	‡2	5	..	*30.83	31.60	[a] APO-Nicorandil [TX]	[a] Ikotab [AF]

nicorandil 20 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13551F NP	‡2	5	..	*37.65	31.60	[a] APO-Nicorandil [TX]	[a] Ikotab [AF]

▪ PERHEXILINE

Note Regular monitoring of drug serum levels is recommended.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5592

Angina

Clinical criteria:

- The condition must not be responding to other therapy.

perhexiline maleate 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1822X NP	1	5	..	54.95	31.60	Pexsig [AS]

▪ VERICIGUAT

Note Special Pricing Arrangements apply.

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

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

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

13561
Chronic heart failure
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

vericiguat 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13192H NP	1	5	..	144.38	31.60	Verquvo [BN]

vericiguat 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13178N NP	1	5	..	144.38	31.60	Verquvo [BN]

vericiguat 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13189E NP	1	5	..	144.38	31.60	Verquvo [BN]

▪ VERICIGUAT

Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note The date of the decompensation event and date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required
Chronic heart failure
Treatment Phase: Initial treatment
Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist.

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%, **AND**
- The condition must be stabilised following a decompensation event that required at least one of: (i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months, **AND**
- Patient must not have clinical signs of fluid overload, **AND**
- Patient must not have received intravenous treatment for fluid overload in the previous 24 hours, **AND**
- Patient must not have a systolic blood pressure less than 100 mmHg, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

vericiguat 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13193J	1	5	..	144.38	31.60	Verquvo [BN]

vericiguat 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13181R	1	5	..	144.38	31.60	Verquvo [BN]

vericiguat 5 mg tablet, 28

13186B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	144.38	31.60	Verquvo [BN]

OTHER CARDIAC PREPARATIONS

Other cardiac preparations

▪ IVABRADINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4979

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

ivabradine 5 mg tablet, 56

10012Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	46.82	31.60	[a] APO-Ivabradine [TX]	[a] Coralan [SE]

ivabradine 7.5 mg tablet, 56

2960T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	46.82	31.60	[a] APO-Ivabradine [TX]	[a] Coralan [SE]

▪ MAVACAMTEN

Caution The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; OR
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

mavacamten 10 mg capsule, 28

14137C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2323.30	31.60	Camzyos [BQ]

mavacamten 15 mg capsule, 28

14139E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2323.30	31.60	Camzyos [BQ]

▪ MAVACAMTEN

Caution The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

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

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

Note Special Pricing Arrangements apply.

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Initial treatment (covering the first 12 weeks of therapy)

Clinical criteria:

- Patient must have confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy, **AND**
- Patient must have maximal end-diastolic left ventricular wall thickness which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have confirmed peak left ventricular outflow tract (LVOT) gradient of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of (a) Valsalva manoeuvre, (b) exercise, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 55%, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be symptomatic with NYHA classes II or III.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

(1) A completed authority prescription form; and

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the left ventricular wall thickness in millimetres (mm).

(4) The details of a genotyping test report if the patient had been tested. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) if a gene has been identified that is associated with HCM;

(c) if any first-degree family relative has a confirmed diagnosis of HCM.

(5) The details of the LVOT gradient report. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the measured LVOT gradient;

(c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).

(6) NYHA status.

(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.

(8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:

(a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;

(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;

(c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.

All results and reports must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; OR
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

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

mavacamten 2.5 mg capsule, 28

14135Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2323.30	31.60	Camzyos [BQ]

mavacamten 5 mg capsule, 28

14117B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2323.30	31.60	Camzyos [BQ]

▪ MAVACAMTEN

Caution The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

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

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

Note Special Pricing Arrangements apply.

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Subsequent continuing treatment - Maintenance treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather arrangements if at least 6 months on optimal dose is achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response after at least 6 months on the optimal dose of mavacamten treatment defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

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

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have had confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have had maximal end-diastolic left ventricular wall thickness, prior to commencing non-PBS-subsidised treatment, which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have had confirmed peak left ventricular outflow tract (LVOT) gradient, prior to commencing non-PBS-subsidised treatment, of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of: (a) Valsalva manoeuvre; (b) exercise, **AND**
- Patient must have had left ventricular ejection fraction (LVEF) of no less than 55% prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless contraindication/ intolerance present, prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have been symptomatic with NYHA classes II or III prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response if received the optimal dose of mavacamten treatment for at least 6 months, defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) LVOT gradient; OR
- Patient must be receiving mavacamten treatment but have not reached at least 6 months on optimal dose to demonstrate a response as defined above.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

(1) A completed authority prescription form; and

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the left ventricular wall thickness in millimetres (mm).

(4) The details of a genotyping test report if the patient had been tested. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) if a gene has been identified that is associated with HCM;

(c) if any first-degree family relative has a confirmed diagnosis of HCM.

(5) The details of the LVOT gradient report. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the measured LVOT gradient;

(c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).

(6) NYHA status.

(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.

(8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:

(a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;

(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;

(c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.

All results and reports must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'maintenance treatment' criteria if at least 6 months on optimal dose of mavacamten treatment is achieved. Where a 'Grandfathered' patient has received fewer than 6 months on optimal dose, or is titrating treatment until optimal dose is achieved, they must qualify under the 'first continuing treatment' criteria.

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

mavacamten 10 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14138D	1	5	..	2323.30	31.60	Camzyos [BQ]

mavacamten 15 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14124J	1	5	..	2323.30	31.60	Camzyos [BQ]

mavacamten 2.5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14123H	1	5	..	2323.30	31.60	Camzyos [BQ]

mavacamten 5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14113T	1	5	..	2323.30	31.60	Camzyos [BQ]

ANTIHYPERTENSIVES

ANTIADRENERGIC AGENTS, CENTRALLY ACTING

Methyldopa

METHYLDOPA

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

Authority required

Hypertension

Population criteria:

- Patient must be pregnant.

methyldopa 250 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1629R NP	1	5	..	22.26	23.71	[a] Aldomet [AS]	[a] Hydopa [AF]

Imidazoline receptor agonists

CLONIDINE

clonidine hydrochloride 100 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3145M NP	1	5	..	25.79	27.24	[a] APO-Clonidine [TX] [a] Clonidine Lupin [GQ]	[a] Catapres 100 [IX]

clonidine hydrochloride 150 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3141H NP	1	5	..	31.96	31.60	Catapres [IX]

CLONIDINE

Restricted benefit

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

clonidine hydrochloride 100 microgram tablet, 100

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*38.13	31.60	[a] APO-Clonidine [TX]	[a] Catapres 100 [IX]

13578P [a] Clonidine Lupin [GQ]

NP

clonidine hydrochloride 150 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13548C NP	2	5	..	*50.47	31.60	Catapres [IX]

▪ GUANFACINE

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

9034

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatrician or psychiatrist.

Clinical criteria:

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

Authority required (STREAMLINED)

9031

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Authority required (STREAMLINED)

8544

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatrician or psychiatrist.

Clinical criteria:

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine), **AND**
- Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

Authority required (STREAMLINED)

8585

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).

guanfacine 1 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11452R	1	5	..	65.30	31.60	Intuniv [TK]

guanfacine 2 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11451Q	1	5	..	65.30	31.60	Intuniv [TK]

guanfacine 3 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11440D	1	5	..	65.30	31.60	Intuniv [TK]

guanfacine 4 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11441E	1	5	..	65.30	31.60	Intuniv [TK]

▪ MOXONIDINE

Restricted benefit

Hypertension

Clinical criteria:

- Patient must be receiving concurrent antihypertensive therapy.

moxonidine 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9019Q NP	1	5	..	18.90	20.35	[a] APO-Moxonidine [TX] [a] Moxonidine GX [SZ] [a] Moxotens [RF]	[a] Moxonidine GH [GQ] [a] Moxonidine Viatris [AL] [a] Physiotens [GO]

moxonidine 400 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9020R NP	1	5	..	22.73	24.18	[a] APO-Moxonidine [TX] [a] Moxonidine GX [SZ] [a] Moxotens [RF]	[a] Moxonidine GH [GQ] [a] Moxonidine Viatris [AL] [a] Physiotens [GO]

▪ MOXONIDINE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving concurrent antihypertensive therapy.

moxonidine 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13579Q NP	2	5	..	*24.35	25.80	[a] APO-Moxonidine [TX] [a] Moxonidine GX [SZ] [a] Moxotens [RF]	[a] Moxonidine GH [GQ] [a] Moxonidine Viatris [AL] [a] Physiotens [GO]

moxonidine 400 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13552G NP	2	5	..	*32.01	31.60	[a] APO-Moxonidine [TX] [a] Moxonidine GX [SZ] [a] Moxotens [RF]	[a] Moxonidine GH [GQ] [a] Moxonidine Viatris [AL] [a] Physiotens [GO]

ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

Alpha-adrenoreceptor antagonists

▪ PRAZOSIN

prazosin 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1480X NP	1	5	..	19.34	20.79	[a] APO-Prazosin [TX]	[a] Minipress [PF]

prazosin 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1478T NP	1	5	..	24.02	25.47	[a] APO-Prazosin [TX]	[a] Minipress [PF]

prazosin 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1479W NP	1	5	..	17.59	19.04	[a] APO-Prazosin [TX]	[a] Minipress [PF]

▪ PRAZOSIN

Restricted benefit

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

prazosin 2 mg tablet, 100

13400G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*25.23	26.68	[a] APO-Prazosin [TX]	[a] Minipress [PF]

prazosin 5 mg tablet, 100

13367M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*34.59	31.60	[a] APO-Prazosin [TX]	[a] Minipress [PF]

prazosin 1 mg tablet, 100

13553H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.73	23.18	[a] APO-Prazosin [TX]	[a] Minipress [PF]

ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

Pyrimidine derivatives

▪ MINOXIDIL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe refractory hypertension

Clinical criteria:

- The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 100

2313R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	44.38	31.60	Loniten [PF]

▪ MINOXIDIL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe refractory hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 100

14041B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*75.31	31.60	Loniten [PF]

▪ DIURETICS

LOW-CEILING DIURETICS, THIAZIDES

Thiazides, plain

▪ HYDROCHLOROTHIAZIDE

hydrochlorothiazide 25 mg tablet, 100

1484D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	21.61	23.06	Dithiazide [FF]

▪ HYDROCHLOROTHIAZIDE

Restricted benefit

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

hydrochlorothiazide 25 mg tablet, 100

13409R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*29.77	31.22	Dithiazide [FF]

LOW-CEILING DIURETICS, EXCL. THIAZIDES

Sulfonamides, plain

▪ CHLORTALIDONE

chlortalidone 25 mg tablet, 50

1585K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*21.35	22.80	Hygroton 25 [GH]

NP

▪ CHLORTALIDONE

Restricted benefit

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

chlortalidone 25 mg tablet, 50

13500M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	1	..	*29.23	30.68	Hygroton 25 [GH]

NP

▪ INDAPAMIDE

indapamide hemihydrate 1.5 mg modified release tablet, 90

8532C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	20.17	21.62	[a] APO-Indapamide SR [TX] [a] Tenaxil SR [RW]	[a] Odaplix SR [AF]
		[B]7.72	27.89	21.62	[a] Natrilix SR [SE]	

NP

indapamide hemihydrate 2.5 mg tablet, 90

2436F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	17.91	19.36	[a] Dapa-Tabs [AF]	[a] Insig [RW]

NP

▪ INDAPAMIDE

Restricted benefit

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

indapamide hemihydrate 1.5 mg modified release tablet, 90

13475F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	..	*26.89	28.34	[a] APO-Indapamide SR [TX] [a] Tenaxil SR [RW]	[a] Odaplix SR [AF]
		[B]15.44	*42.33	28.34	[a] Natrilix SR [SE]	

NP

indapamide hemihydrate 2.5 mg tablet, 90

13378D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	..	*22.37	23.82	[a] Dapa-Tabs [AF]	[a] Insig [RW]

NP

HIGH-CEILING DIURETICS

Sulfonamides, plain

▪ FUROSEMIDE

furosemide 20 mg/2 mL injection, 5 x 2 mL ampoules

2413B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	16.58	18.03	Lasix [SW]

NP

furosemide 10 mg/mL oral liquid, 30 mL

2411X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	29.48	30.93	Lasix [SW]

NP

furosemide 40 mg tablet, 100

2412Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	16.17	17.62	[a] APO-Frusemide [TX] [a] NOUMED FUROSEMIDE [VO]	[a] Frusax [ZS] [a] Uremide [AF]
		[B]1.04	17.21	17.62	[a] Frusemix [TY]	

NP

furosemide 500 mg tablet, 50

2415D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	23.27	24.72	Urex-Forte [RW]

NP

▪ FUROSEMIDE

Restricted benefit

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

furosemide 10 mg/mL oral liquid, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13504R NP	‡2	3	..	*45.51	31.60	Lasix [SW]

furosemide 40 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13472C NP	2	1	..	*18.89	20.34	[a] APO-Frusemide [TX]	[a] Frusax [ZS]
						[a] NOUMED FUROSEMIDE [VO]	[a] Uremide [AF]
			[B]2.08	*20.97	20.34	[a] Frusemix [TY]	

furosemide 500 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13474E NP	2	3	..	*33.09	31.60	Urex-Forte [RW]

▪ FUROSEMIDE

Note For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

furosemide 20 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1810G NP	2	1	..	*18.85	20.30	[a] Frusemix-M [TY]	[a] UREMIDE 20 [AF]

furosemide 20 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2414C NP	1	1	..	18.84	20.29	[a] APO-Frusemide [TX]	[a] UREMIDE 20 [AF]
			[B]1.06	19.90	20.29	[a] Frusemix-M [TY]	

▪ FUROSEMIDE

Note Pharmaceutical benefits that have the form furosemide 20 mg tablet, 50 and pharmaceutical benefits that have the form furosemide 20 mg tablet, 100 are equivalent for the purposes of substitution.

Restricted benefit

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

furosemide 20 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13501N NP	4	1	..	*24.23	25.68	[a] Frusemix-M [TY]	[a] UREMIDE 20 [AF]

furosemide 20 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13473D NP	2	1	..	*24.23	25.68	[a] APO-Frusemide [TX]	[a] UREMIDE 20 [AF]
			[B]2.12	*26.35	25.68	[a] Frusemix-M [TY]	

ALDOSTERONE ANTAGONISTS AND OTHER POTASSIUM-SPARING AGENTS

Aldosterone antagonists

▪ EPLERENONE

Caution Serum electrolytes should be checked regularly

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4937

Heart failure with a left ventricular ejection fraction of 40% or less

Clinical criteria:

- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

eplerenone 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8879H NP	1	5	..	54.09	31.60	[a] APO-Eplerenone [TX]	[a] ESPLER [RW]
						[a] Inpler [AF]	[a] Inspra [UJ]

eplerenone 50 mg tablet, 30

8880J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	54.09	31.60	[a] APO-Eplerenone [TX] [a] Inpler [AF]	[a] ESPLER [RW] [a] Inspra [UJ]

NP

▪ EPLERENONE

Caution Serum electrolytes should be checked regularly

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14266

Heart failure with a left ventricular ejection fraction of 40% or less

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

eplerenone 25 mg tablet, 30

13590G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*94.73	31.60	[a] APO-Eplerenone [TX] [a] Inpler [AF]	[a] ESPLER [RW] [a] Inspra [UJ]

NP

eplerenone 50 mg tablet, 30

13379E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*94.73	31.60	[a] APO-Eplerenone [TX] [a] Inpler [AF]	[a] ESPLER [RW] [a] Inspra [UJ]

NP

▪ FINERENONE

Caution Serum electrolytes should be checked regularly

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14097

Chronic kidney disease with Type 2 diabetes

Clinical criteria:

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m^2 or greater, prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug, **AND**
- The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant, **AND**
- Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic, **AND**
- Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.

finerenone 10 mg tablet, 28

13335W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	84.51	31.60	Kerendia [BN]

NP

finerenone 20 mg tablet, 28

13316W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	84.51	31.60	Kerendia [BN]

NP

▪ SPIRONOLACTONE

Caution Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

spironolactone 100 mg tablet, 100

2340E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	28.27	29.72	[a] Spironolactone Viatris 100 [AL]
		[B]4.50	32.77	29.72	[a] Spiractin 100 [AF]
		[B]7.50	35.77	29.72	[a] Aldactone [PF]

spironolactone 25 mg tablet, 100

2339D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.22	18.67	[a] Spironolactone Viatris 25 [AL]
		[B]4.65	21.87	18.67	[a] Spiractin 25 [AF]
		[B]7.65	24.87	18.67	[a] Aldactone [PF]

▪ SPIRONOLACTONE

Caution Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

Restricted benefit

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

spironolactone 100 mg tablet, 100

14042C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*43.09	31.60	[a] Spironolactone Viatris 100 [AL]
		[B]9.00	*52.09	31.60	[a] Spiractin 100 [AF]
		[B]15.00	*58.09	31.60	[a] Aldactone [PF]

spironolactone 25 mg tablet, 100

13503Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] Spironolactone Viatris 25 [AL]
		[B]9.30	*30.29	22.44	[a] Spiractin 25 [AF]
		[B]15.30	*36.29	22.44	[a] Aldactone [PF]

DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

Low-ceiling diuretics and potassium-sparing agents

▪ AMILORIDE + HYDROCHLOROTHIAZIDE

Caution Serum electrolytes should be checked regularly.

amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50

1486F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*23.61	25.06	Moduretic [AS]

▪ AMILORIDE + HYDROCHLOROTHIAZIDE

Caution Serum electrolytes should be checked regularly.

Restricted benefit

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

amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50

13410T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	1	..	*33.75	31.60	Moduretic [AS]

OTHER DIURETICS

Vasopressin antagonists

▪ TOLVAPTAN

Caution Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

Note Special Pricing Arrangements apply.

Authority required

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 m^2 at the initiation of treatment with this drug for this condition, **AND**
- Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition.

Rapidly progressing disease is defined as either of the following:

A decline in eGFR of greater than or equal to 5 mL/min/1.73 m^2 within one year;

OR

An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m^2 per year over a five year period.

tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11602P	1	5	..	1741.11	31.60	Jinarc [OS]

tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11597J	1	5	..	1741.11	31.60	Jinarc [OS]

tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11588X	1	5	..	1741.11	31.60	Jinarc [OS]

tolvaptan 15 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12460T	1	5	..	903.21	31.60	Jinarc [OS]

tolvaptan 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12461W	1	5	..	903.21	31.60	Jinarc [OS]

▪ TOLVAPTAN

Caution Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8288

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a nephrologist or in consultation with a nephrologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m^2, **AND**
- Patient must not have had a kidney transplant.

tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11600M	1	5	..	1741.11	31.60	Jinarc [OS]

tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11593E	1	5	..	1741.11	31.60	Jinarc [OS]

tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11596H	1	5	..	1741.11	31.60	Jinarc [OS]

tolvaptan 15 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12457P	1	5	..	903.21	31.60	Jinarc [OS]

tolvaptan 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12462X	1	5	..	903.21	31.60	Jinarc [OS]

▪ PERIPHERAL VASODILATORS

PERIPHERAL VASODILATORS

Other peripheral vasodilators

▪ PHENOXYBENZAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1166J NP	3	5	..	*678.33	31.60	Amdipharm Mercury (Australia) Pty Limited [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1862B NP	1	5	..	752.77	31.60	Dibenyline [GH]

▪ BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

Beta blocking agents, non-selective

▪ OXPRENOLOL

oxprenolol hydrochloride 40 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2961W NP	1	5	..	37.04	31.60	Corbeton 40 [AF]

▪ PROPRANOLOL

propranolol hydrochloride 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2565B NP	1	5	..	16.75	18.20	[a] APO-Propranolol [TX]
			[B]2.99	19.74	18.20	[a] Deralin 10 [AF]
			[B]8.48	25.23	18.20	[a] Inderal [IX]

propranolol hydrochloride 40 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2566C NP	1	5	..	17.02	18.47	[a] APO-Propranolol [TX]
			[B]2.99	20.01	18.47	[a] Deralin 40 [AF]
			[B]8.48	25.50	18.47	[a] Inderal [IX]

▪ PROPRANOLOL

Restricted benefit

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

propranolol hydrochloride 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13386M NP	2	5	..	*20.05	21.50	[a] APO-Propranolol [TX]
			[B]5.98	*26.03	21.50	[a] Deralin 10 [AF]
			[B]16.96	*37.01	21.50	[a] Inderal [IX]

propranolol hydrochloride 40 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13542R NP	2	5	..	*20.59	22.04	[a] APO-Propranolol [TX]
			[B]5.98	*26.57	22.04	[a] Deralin 40 [AF]
			[B]16.96	*37.55	22.04	[a] Inderal [IX]

Beta blocking agents, selective

▪ ATENOLOL

atenolol 50 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1081X NP	1	5	..	16.17	17.62	[a] APO-Atenolol [TX] [a] Atenolol GH [GQ] [a] Blooms The Chemist Atenolol [BG] [a] Tensig [RW]	[a] APX-Atenolol [TY] [a] Atenolol Sandoz [SZ] [a] Noten [AF]
			[B]13.44	29.61	17.62	[a] Tenormin [IX]	

▪ ATENOLOL

Restricted benefit

For a patient who is unable to take a solid dose form of atenolol.

atenolol 50 mg/10 mL oral liquid, 300 mL

2243C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	46.78	31.60	Atenolol-AFT [AE]

▪ ATENOLOL

Restricted benefit

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

atenolol 50 mg tablet, 30

13540P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] APO-Atenolol [TX] [a] Atenolol GH [GQ] [a] Blooms The Chemist Atenolol [BG] [a] Tensig [RW]	[a] APX-Atenolol [TY] [a] Atenolol Sandoz [SZ] [a] Noten [AF]
		[B]26.88	*45.77	20.34	[a] Tenormin [IX]	

▪ ATENOLOL

Restricted benefit

For a patient who is unable to take a solid dose form of atenolol.

Clinical criteria:

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

atenolol 50 mg/10 mL oral liquid, 300 mL

13600T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*80.11	31.60	Atenolol-AFT [AE]

▪ BISOPROLOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

bisoprolol fumarate 10 mg tablet, 28

8606Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.00	20.45	[a] APO-Bisoprolol [TX] [a] Bisoprolol generichealth [GQ] [a] Bispro 10 [AF] [a] NOUMED BISOPROLOL [VO]	[a] Bicard 10 [RW] [a] Bisoprolol Sandoz [SZ] [a] Cipla Bisoprolol [LR]
		[B]4.51	23.51	20.45	[a] Bicor [AL]	

bisoprolol fumarate 2.5 mg tablet, 28

8604W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] APO-Bisoprolol [TX] [a] Bisoprolol generichealth [GQ] [a] Bispro 2.5 [AF] [a] NOUMED BISOPROLOL [VO]	[a] Bicard 2.5 [RW] [a] Bisoprolol Sandoz [SZ] [a] Cipla Bisoprolol [LR]
		[B]5.51	23.27	19.21	[a] Bicor [AL]	

bisoprolol fumarate 5 mg tablet, 28

8605X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.89	19.34	[a] APO-Bisoprolol [TX] [a] Bisoprolol generichealth [GQ] [a] Bispro 5 [AF] [a] NOUMED BISOPROLOL [VO]	[a] Bicard 5 [RW] [a] Bisoprolol Sandoz [SZ] [a] Cipla Bisoprolol [LR]
		[B]4.50	22.39	19.34	[a] Bicor [AL]	

▪ BISOPROLOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

bisoprolol fumarate 10 mg tablet, 28

13444N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*24.55	26.00	[a] APO-Bisoprolol [TX] [a] Bisoprolol generichealth [GQ] [a] Bispro 10 [AF] [a] NOUMED BISOPROLOL [VO]	[a] Bicard 10 [RW] [a] Bisoprolol Sandoz [SZ] [a] Cipla Bisoprolol [LR]
		[B]9.02	*33.57	26.00	[a] Bicor [AL]	

bisoprolol fumarate 2.5 mg tablet, 28

13419G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] APO-Bisoprolol [TX] [a] Bisoprolol generichealth [GQ] [a] Bispro 2.5 [AF] [a] NOUMED BISOPROLOL [VO]	[a] Bicard 2.5 [RW] [a] Bisoprolol Sandoz [SZ] [a] Cipla Bisoprolol [LR]
		[B]11.02	*33.09	23.52	[a] Bicor [AL]	

bisoprolol fumarate 5 mg tablet, 28

13443M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.33	23.78	[a] APO-Bisoprolol [TX] [a] Bisoprolol generichealth [GQ] [a] Bispro 5 [AF] [a] NOUMED BISOPROLOL [VO]	[a] Bicard 5 [RW] [a] Bisoprolol Sandoz [SZ] [a] Cipla Bisoprolol [LR]
		[B]9.00	*31.33	23.78	[a] Bicor [AL]	

▪ METOPROLOL SUCCINATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

8735R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	41.92	31.60	[a] Metrol-XL 190 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF] [a] Toprol-XL 190 [AP]

METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

8732N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.87	19.32	[a] Metrol-XL 23.75 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF]

METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

8733P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	31.67	31.60	[a] Metrol-XL 47.5 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF] [a] Toprol-XL 47.5 [AP]

METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

8734Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	36.22	31.60	[a] Metrol-XL 95 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF] [a] Toprol-XL 95 [AP]

▪ METOPROLOL SUCCINATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13420H NP	2	5	..	*70.39	31.60	[a] Metrol-XL 190 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF] [a] Toprol-XL 190 [AP]

METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13543T NP	2	5	..	*49.89	31.60	[a] Metrol-XL 47.5 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF] [a] Toprol-XL 47.5 [AP]

METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13544W NP	2	5	..	*58.99	31.60	[a] Metrol-XL 95 [RW] [a] Topreloc-XL [CR]	[a] Minax XL [AF] [a] Toprol-XL 95 [AP]

▪ METOPROLOL TARTRATE

METOPROLOL TARTRATE Tablet 100 mg, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1325R NP	1	5	..	16.43	17.88	Mistrom [ZS] [a] APO-Metoprolol [TX] [a] Metrol 100 [RW] [a] NOUMED METOPROLOL [VO]	[a] Metoprolol Sandoz [SZ] [a] Minax 100 [AF]
			[B]13.15	29.58	17.88	[a] Betaloc [AP]	

METOPROLOL TARTRATE Tablet 50 mg, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1324Q NP	1	5	..	16.17	17.62	Mistrom [ZS] [a] APO-Metoprolol [TX] [a] Metrol 50 [RW] [a] NOUMED METOPROLOL [VO]	[a] Metoprolol Sandoz [SZ] [a] Minax 50 [AF]
			[B]13.15	29.32	17.62	[a] Betaloc [AP]	

▪ METOPROLOL TARTRATE

Restricted benefit

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

METOPROLOL TARTRATE Tablet 100 mg, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13541Q NP	2	5	..	*19.41	20.86	Mistrom [ZS] [a] APO-Metoprolol [TX] [a] Metrol 100 [RW] [a] NOUMED METOPROLOL [VO]	[a] Metoprolol Sandoz [SZ] [a] Minax 100 [AF]
			[B]26.30	*45.71	20.86	[a] Betaloc [AP]	

METOPROLOL TARTRATE Tablet 50 mg, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13598Q NP	2	5	..	*18.89	20.34	Mistrom [ZS] [a] APO-Metoprolol [TX] [a] Metrol 50 [RW] [a] NOUMED METOPROLOL [VO]	[a] Metoprolol Sandoz [SZ] [a] Minax 50 [AF]
			[B]26.30	*45.19	20.34	[a] Betaloc [AP]	

▪ NEBIVOLOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

nebivolol 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9312D NP	1	5	..	43.14	31.60	[a] APO-Nebivolol [TX] [a] Nebivolol Lupin [GQ] [a] Nepiten [AF]	[a] Nebilet [FK] [a] Nebivolol Sandoz [SZ]

nebivolol 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9311C NP	1	5	..	39.72	31.60	[a] APO-Nebivolol [TX] [a] Nebivolol Lupin [GQ] [a] Nepiten [AF]	[a] Nebilet [FK] [a] Nebivolol Sandoz [SZ]

nebivolol 1.25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9316H NP	2	5	..	*34.51	31.60	[a] APO-Nebivolol [TX] [a] Nebivolol Lupin [GQ] [a] Nepiten [AF]	[a] Nebilet [FK] [a] Nebivolol Sandoz [SZ]

▪ NEBIVOLOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

nebivolol 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13441K NP	2	5	..	*72.83	31.60	[a] APO-Nebivolol [TX] [a] Nebivolol Lupin [GQ] [a] Nepiten [AF]	[a] Nebilet [FK] [a] Nebivolol Sandoz [SZ]

nebivolol 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13510C NP	2	5	..	*65.99	31.60	[a] APO-Nebivolol [TX] [a] Nebivolol Lupin [GQ] [a] Nepiten [AF]	[a] Nebilet [FK] [a] Nebivolol Sandoz [SZ]

nebivolol 1.25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13568D NP	4	5	..	*55.55	31.60	[a] APO-Nebivolol [TX] [a] Nebivolol Lupin [GQ] [a] Nepiten [AF]	[a] Nebilet [FK] [a] Nebivolol Sandoz [SZ]

Alpha and beta blocking agents

▪ CARVEDILOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Restricted benefit

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

carvedilol 12.5 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8257N NP	1	5	..	18.89	20.34	[a] APO-Carvedilol [TX] [a] Carvidol [RF] [a] Dilatrend 12.5 [PB] [a] Volirop 12.5 [ZS]	[a] Carvedilol Sandoz [SZ] [a] Dicarz [AF] [a] Vedilol 12.5 [RW]

carvedilol 25 mg tablet, 60

8258P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.24	21.69	[a] APO-Carvedilol [TX] [a] Carvidol [RF] [a] Dilatrend 25 [PB] [a] Volirop 25 [ZS]	[a] Carvedilol Sandoz [SZ] [a] Dicarz [AF] [a] Vedilol 25 [RW]

carvedilol 3.125 mg tablet, 30

8255L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.20	18.65	[a] APO-Carvedilol [TX] [a] Vedilol 3.125 [RW]	[a] Carvidol [RF] [a] Volirop 3.125 [ZS]

carvedilol 6.25 mg tablet, 60

8256M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.80	19.25	[a] APO-Carvedilol [TX] [a] Carvidol [RF] [a] Dilatrend 6.25 [PB] [a] Volirop 6.25 [ZS]	[a] Carvedilol Sandoz [SZ] [a] Dicarz [AF] [a] Vedilol 6.25 [RW]

▪ CARVEDILOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Restricted benefit

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

Clinical criteria:

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

carvedilol 12.5 mg tablet, 60

13418F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*24.33	25.78	[a] APO-Carvedilol [TX] [a] Carvidol [RF] [a] Dilatrend 12.5 [PB] [a] Volirop 12.5 [ZS]	[a] Carvedilol Sandoz [SZ] [a] Dicarz [AF] [a] Vedilol 12.5 [RW]

carvedilol 25 mg tablet, 60

13387N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*27.03	28.48	[a] APO-Carvedilol [TX] [a] Carvidol [RF] [a] Dilatrend 25 [PB] [a] Volirop 25 [ZS]	[a] Carvedilol Sandoz [SZ] [a] Dicarz [AF] [a] Vedilol 25 [RW]

carvedilol 6.25 mg tablet, 60

13417E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.15	23.60	[a] APO-Carvedilol [TX] [a] Carvidol [RF] [a] Dilatrend 6.25 [PB] [a] Volirop 6.25 [ZS]	[a] Carvedilol Sandoz [SZ] [a] Dicarz [AF] [a] Vedilol 6.25 [RW]

▪ LABETALOL

labetalol hydrochloride 100 mg tablet, 100

1566K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	26.71	28.16	Presolol 100 [AF]

▪ LABETALOL

Restricted benefit

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

labetalol hydrochloride 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13887X NP	2	5	..	*39.97	31.60	Presolol 100 [AF]

▪ CALCIUM CHANNEL BLOCKERS

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

Dihydropyridine derivatives

▪ AMLODIPINE

amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2751T NP	1	5	..	16.17	17.62	[a] Amlo 5 [RW]	[a] Amlodipine APOTEX [GX]
						[a] Amlodipine GH [GQ]	[a] Amlodipine Sandoz [SZ]
						[a] APO-Amlodipine [TX]	[a] APX-AMLODIPINE [TW]
						[a] Blooms Amlodipine [BG]	[a] Blooms the Chemist Amlodipine [IB]
						[a] BTC Amlodipine [JB]	[a] Nordip [AF]
						[a] NOUMED AMLODIPINE [VO]	[a] Pharmacor Amlodipine [CR]
			[B]11.17	27.34	17.62	[a] Norvasc [AS]	

amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2752W NP	1	5	..	16.17	17.62	[a] Amlo 10 [RW]	[a] Amlodipine APOTEX [GX]
						[a] Amlodipine GH [GQ]	[a] Amlodipine Sandoz [SZ]
						[a] APO-Amlodipine [TX]	[a] Blooms Amlodipine [BG]
						[a] Blooms the Chemist Amlodipine [IB]	[a] BTC Amlodipine [JB]
						[a] Nordip [AF]	[a] NOUMED AMLODIPINE [VO]
						[a] Pharmacor Amlodipine [CR]	
			[B]11.18	27.35	17.62	[a] Norvasc [AS]	

▪ AMLODIPINE

Restricted benefit

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

amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13532F NP	2	5	..	*18.89	20.34	[a] Amlo 5 [RW]	[a] Amlodipine APOTEX [GX]
						[a] Amlodipine GH [GQ]	[a] Amlodipine Sandoz [SZ]
						[a] APO-Amlodipine [TX]	[a] APX-AMLODIPINE [TW]
						[a] Blooms Amlodipine [BG]	[a] Blooms the Chemist Amlodipine [IB]
						[a] BTC Amlodipine [JB]	[a] Nordip [AF]
						[a] NOUMED AMLODIPINE [VO]	[a] Pharmacor Amlodipine [CR]
			[B]22.34	*41.23	20.34	[a] Norvasc [AS]	

amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13562T NP	2	5	..	*18.89	20.34	[a] Amlo 10 [RW]	[a] Amlodipine APOTEX [GX]
						[a] Amlodipine GH [GQ]	[a] Amlodipine Sandoz [SZ]
						[a] APO-Amlodipine [TX]	[a] Blooms Amlodipine [BG]
						[a] Blooms the Chemist Amlodipine [IB]	[a] BTC Amlodipine [JB]
						[a] Nordip [AF]	[a] NOUMED AMLODIPINE [VO]
						[a] Pharmacor Amlodipine [CR]	
			[B]22.36	*41.25	20.34	[a] Norvasc [AS]	

▪ FELODIPINE

felodipine 10 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2367N NP	1	5	..	20.76	22.21	[a] Felodil XR 10 [RW]	[a] Felodur ER 10 mg [TX]
						[a] Fendex ER [AF]	
			[B]3.75	24.51	22.21	[a] Plendil ER [GX]	

felodipine 2.5 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2361G NP	1	5	..	16.80	18.25	[a] Felodur ER 2.5 mg [TX]	[a] Fendex ER [AF]
			[B]3.97	20.77	18.25	[a] Plendil ER [GX]	

felodipine 5 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2366M NP	1	5	..	17.49	18.94	[a] Felodil XR 5 [RW] [a] Fendex ER [AF]	[a] Felodur ER 5 mg [TX]
			[B]3.88	21.37	18.94	[a] Plendil ER [GX]	

▪ FELODIPINE

Restricted benefit

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

felodipine 10 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13531E NP	2	5	..	*28.07	29.52	[a] Felodil XR 10 [RW] [a] Fendex ER [AF]	[a] Felodur ER 10 mg [TX]
			[B]7.50	*35.57	29.52	[a] Plendil ER [GX]	

felodipine 2.5 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13377C NP	2	5	..	*20.15	21.60	[a] Felodur ER 2.5 mg [TX]	[a] Fendex ER [AF]
			[B]7.94	*28.09	21.60	[a] Plendil ER [GX]	

felodipine 5 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13561R NP	2	5	..	*21.53	22.98	[a] Felodil XR 5 [RW] [a] Fendex ER [AF]	[a] Felodur ER 5 mg [TX]
			[B]7.76	*29.29	22.98	[a] Plendil ER [GX]	

▪ LERCANIDIPINE

lercanidipine hydrochloride 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8534E NP	1	5	..	16.17	17.62	[a] ARX-LERCANIDIPINE [TX] [a] Lercan [RW] [a] Zircol 10 [AL]	[a] BTC Lercanidipine [JB] [a] Lercanidipine APOTEX [GX]
			[B]3.48	19.65	17.62	[a] Zanidip [GO]	

lercanidipine hydrochloride 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8679T NP	1	5	..	17.22	18.67	[a] ARX-LERCANIDIPINE [TX] [a] Lercan [RW] [a] Zircol 20 [AL]	[a] BTC Lercanidipine [JB] [a] Lercanidipine APOTEX [GX]
			[B]3.50	20.72	18.67	[a] Zanidip [GO]	

▪ LERCANIDIPINE

Restricted benefit

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

lercanidipine hydrochloride 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13411W NP	2	5	..	*18.89	20.34	[a] ARX-LERCANIDIPINE [TX] [a] Lercan [RW] [a] Zircol 10 [AL]	[a] BTC Lercanidipine [JB] [a] Lercanidipine APOTEX [GX]
			[B]6.96	*25.85	20.34	[a] Zanidip [GO]	

lercanidipine hydrochloride 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13412X NP	2	5	..	*20.99	22.44	[a] ARX-LERCANIDIPINE [TX] [a] Lercan [RW] [a] Zircol 20 [AL]	[a] BTC Lercanidipine [JB] [a] Lercanidipine APOTEX [GX]
			[B]7.00	*27.99	22.44	[a] Zanidip [GO]	

▪ NIFEDIPINE

nifedipine 30 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1906H NP	1	5	..	20.35	21.80	[a] Addos XR 30 [RW]	[a] APO-Nifedipine XR [TX]

nifedipine 60 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1907J NP	1	5	..	22.12	23.57	[a] Addos XR 60 [RW]	[a] APO-Nifedipine XR [TX]

▪ NIFEDIPINE

Restricted benefit

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

nifedipine 30 mg modified release tablet, 30

13502P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*27.25	28.70	[a] Addos XR 30 [RW]	[a] APO-Nifedipine XR [TX]

nifedipine 60 mg modified release tablet, 30

13376B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*30.79	31.60	[a] Addos XR 60 [RW]	[a] APO-Nifedipine XR [TX]

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

Phenylalkylamine derivatives

▪ VERAPAMIL

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

verapamil hydrochloride 180 mg modified release tablet, 30

2208F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18.80	20.25	[a] Cordilox 180 SR [GT]
		[B]3.54	22.34	20.25	[a] Isoptin 180 SR [GO]

verapamil hydrochloride 240 mg modified release tablet, 30

1241H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	20.59	22.04	[a] Cordilox SR [GT]
		[B]3.50	24.09	22.04	[a] Isoptin SR [GO]

verapamil hydrochloride 80 mg tablet, 100

1250T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	20.08	21.53	[a] Anpec 80 [AF]
		[B]3.10	23.18	21.53	[a] Isoptin [GO]

▪ VERAPAMIL

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

Restricted benefit

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

verapamil hydrochloride 180 mg modified release tablet, 30

13434C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*24.15	25.60	[a] Cordilox 180 SR [GT]
		[B]7.08	*31.23	25.60	[a] Isoptin 180 SR [GO]

verapamil hydrochloride 240 mg modified release tablet, 30

13408Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*27.73	29.18	[a] Cordilox SR [GT]
		[B]7.00	*34.73	29.18	[a] Isoptin SR [GO]

verapamil hydrochloride 80 mg tablet, 100

13530D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*26.71	28.16	[a] Anpec 80 [AF]
		[B]6.20	*32.91	28.16	[a] Isoptin [GO]

Benzothiazepine derivatives

▪ DILTIAZEM

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

diltiazem hydrochloride 180 mg modified release capsule, 30

1312C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.18	21.63	[a] Diltiazem Sandoz CD [SZ]	[a] Vasocardol CD [AV]
		[B]1.90	22.08	21.63	[a] Cardizem CD [SW]	

diltiazem hydrochloride 240 mg modified release capsule, 30

1313D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	22.55	24.00	[a] Diltiazem Sandoz CD [SZ]	[a] Vasocardol CD [AV]
		[B]1.90	24.45	24.00	[a] Cardizem CD [SW]	

diltiazem hydrochloride 360 mg modified release capsule, 30

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	25.37	26.82	[a] Diltiazem Sandoz CD [SZ]	[a] Vasocardol CD [AV]

8480H			[B]1.90	27.27	26.82	[a] Cardizem CD [SW]

NP

diltiazem hydrochloride 60 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1335G	1	5	..	21.42	22.87	[a] Vasocardol [AV]
			[B]1.90	23.32	22.87	[a] Cardizem [SW]

NP

▪ AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

ACE INHIBITORS, PLAIN

ACE inhibitors, plain

▪ CAPTOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Patients unable to take a solid dose form of an ACE inhibitor.

captopril 5 mg/mL oral liquid, 95 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8760C	‡1	5	..	109.28	31.60	Capoten [RW]

NP

▪ ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

enalapril maleate 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1368B	1	5	..	17.08	18.53	[a] Acetec [AL] [a] Enalapril Sandoz [SZ]	[a] APO-Enalapril [TX] [a] Malean [RW]
			[B]10.41	27.49	18.53	[a] Renitec [AF]	

NP

enalapril maleate 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1369C	1	5	..	17.38	18.83	[a] Acetec [AL] [a] Enalapril generichealth [GQ] [a] Malean [RW]	[a] APO-Enalapril [TX] [a] Enalapril Sandoz [SZ]
			[B]10.40	27.78	18.83	[a] Renitec 20 [AF]	

NP

enalapril maleate 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1370D	1	5	..	16.17	17.62	[a] Acetec [AL] [a] Enalapril Sandoz [SZ]	[a] APO-Enalapril [TX] [a] Malean [RW]

NP

▪ ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

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

enalapril maleate 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13465Q	2	5	..	*20.71	22.16	[a] Acetec [AL] [a] Enalapril Sandoz [SZ]	[a] APO-Enalapril [TX] [a] Malean [RW]
			[B]20.82	*41.53	22.16	[a] Renitec [AF]	

NP

enalapril maleate 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13401H	2	5	..	*21.31	22.76	[a] Acetec [AL] [a] Enalapril generichealth [GQ] [a] Malean [RW]	[a] APO-Enalapril [TX] [a] Enalapril Sandoz [SZ]
			[B]20.80	*42.11	22.76	[a] Renitec 20 [AF]	

NP

enalapril maleate 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13369P	2	5	..	*18.89	20.34	[a] Acetec [AL] [a] Enalapril Sandoz [SZ]	[a] APO-Enalapril [TX] [a] Malean [RW]

NP

▪ FOSINOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

fosinopril sodium 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1182F							
NP	1	5	..	18.05	19.50	[a] APO-Fosinopril [TX]	[a] Monace 10 [AF]

fosinopril sodium 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1183G							
NP	1	5	..	20.17	21.62	[a] APO-Fosinopril [TX]	[a] Monace 20 [AF]

▪ LISINOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

lisinopril 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2457H							
NP	1	5	..	17.22	18.67	[a] APO-Lisinopril [TX] [a] Lisinopril Sandoz [SZ]	[a] Fibsol 10 [RW] [a] Zinopril 10 [AL]
			[B]4.84	22.06	18.67	[a] Zestril [IX]	

lisinopril 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2458J							
NP	1	5	..	17.54	18.99	[a] APO-Lisinopril [TX] [a] Lisinopril generichealth [GQ] [a] Zinopril 20 [AL]	[a] Fibsol 20 [RW] [a] Lisinopril Sandoz [SZ]
			[B]4.83	22.37	18.99	[a] Zestril [IX]	

lisinopril 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2456G							
NP	1	5	..	16.18	17.63	[a] APO-Lisinopril [TX] [a] Lisinopril Sandoz [SZ]	[a] Fibsol 5 [RW] [a] Zinopril 5 [AL]
			[B]4.82	21.00	17.63	[a] Zestril [IX]	

▪ LISINOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

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

lisinopril 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13584Y							
NP	2	5	..	*20.99	22.44	[a] APO-Lisinopril [TX] [a] Lisinopril Sandoz [SZ]	[a] Fibsol 10 [RW] [a] Zinopril 10 [AL]
			[B]9.68	*30.67	22.44	[a] Zestril [IX]	

lisinopril 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13402J							
NP	2	5	..	*21.63	23.08	[a] APO-Lisinopril [TX] [a] Lisinopril generichealth [GQ] [a] Zinopril 20 [AL]	[a] Fibsol 20 [RW] [a] Lisinopril Sandoz [SZ]
			[B]9.66	*31.29	23.08	[a] Zestril [IX]	

lisinopril 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13583X							
NP	2	5	..	*18.91	20.36	[a] APO-Lisinopril [TX] [a] Lisinopril Sandoz [SZ]	[a] Fibsol 5 [RW] [a] Zinopril 5 [AL]
			[B]9.64	*28.55	20.36	[a] Zestril [IX]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9006B							
NP	1	5	..	16.17	17.62	[a] APO-Perindopril Arginine [TX] [a] Perindopril Arginine Sandoz [SZ]	[a] APX-Perindopril Arginine [XT] [a] PREXUM 2.5 [RX]

			[B]9.74	25.91	17.62	[a] Coversyl 2.5mg [SE]	

perindopril erbumine 2 mg tablet, 30

3050M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] BTC Perindopril [JB]	[a] Idaprex 2 [SZ]
						[a] Indosyl Mono 2 [RW]	[a] Perindo [AF]
						[a] PERISYL [AL]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 5 mg tablet, 30

9007C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.86	18.31	[a] APO-Perindopril Arginine [TX]	[a] APX-Perindopril Arginine [XT]
						[a] Perindopril Arginine Sandoz [SZ]	[a] PREXUM 5 [RX]
			[B]9.45	26.31	18.31	[a] Coversyl 5mg [SE]	

perindopril erbumine 4 mg tablet, 30

3051N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.86	18.31	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] BTC Perindopril [JB]	[a] Idaprex 4 [SZ]
						[a] Indosyl Mono 4 [RW]	[a] Perindo [AF]
						[a] PERISYL [AL]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 10 mg tablet, 30

9008D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.84	19.29	[a] APO-Perindopril Arginine [TX]	[a] APX-Perindopril Arginine [XT]
						[a] Perindopril Arginine Sandoz [SZ]	[a] PREXUM 10 [RX]
			[B]9.92	27.76	19.29	[a] Coversyl 10mg [SE]	

perindopril erbumine 8 mg tablet, 30

8704D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.84	19.29	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] BTC Perindopril [JB]	[a] Idaprex 8 [SZ]
						[a] Indosyl Mono 8 [RW]	[a] Perindo [AF]
						[a] PERISYL [AL]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

Restricted benefit

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

perindopril arginine 5 mg tablet, 30

13585B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.27	21.72	[a] APO-Perindopril Arginine [TX]	[a] APX-Perindopril Arginine [XT]
						[a] Perindopril Arginine Sandoz [SZ]	[a] PREXUM 5 [RX]
			[B]18.90	*39.17	21.72	[a] Coversyl 5mg [SE]	

perindopril erbumine 4 mg tablet, 30

13371R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.27	21.72	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] BTC Perindopril [JB]	[a] Idaprex 4 [SZ]

						[a] Indosyl Mono 4 [RW]	[a] Perindo [AF]
						[a] PERISYL [AL]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

Restricted benefit

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

perindopril arginine 10 mg tablet, 30

13555K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.23	23.68	[a] APO-Perindopril Arginine [TX]	[a] APX-Perindopril Arginine [XT]
						[a] Perindopril Arginine Sandoz [SZ]	[a] PREXUM 10 [RX]
			[B]19.84	*42.07	23.68	[a] Coversyl 10mg [SE]	

perindopril erbumine 8 mg tablet, 30

13372T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.23	23.68	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] BTC Perindopril [JB]	[a] Idaprex 8 [SZ]
						[a] Indosyl Mono 8 [RW]	[a] Perindo [AF]
						[a] PERISYL [AL]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

Restricted benefit

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

perindopril arginine 2.5 mg tablet, 30

13494F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] APO-Perindopril Arginine [TX]	[a] APX-Perindopril Arginine [XT]
						[a] Perindopril Arginine Sandoz [SZ]	[a] PREXUM 2.5 [RX]
			[B]19.48	*38.37	20.34	[a] Coversyl 2.5mg [SE]	

perindopril erbumine 2 mg tablet, 30

13404L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] BTC Perindopril [JB]	[a] Idaprex 2 [SZ]
						[a] Indosyl Mono 2 [RW]	[a] Perindo [AF]
						[a] PERISYL [AL]	

▪ QUINAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

quinapril 10 mg tablet, 30

1969P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.58	19.03	[a] ACQUIN [RF]	[a] APO-Quinapril [TX]
			[B]4.07	21.65	19.03	[a] Accupril [PF]	

quinapril 20 mg tablet, 30

1970Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.45	19.90	[a] ACQUIN [RF]	[a] APO-Quinapril [TX]
			[B]4.20	22.65	19.90	[a] Accupril [PF]	

quinapril 5 mg tablet, 30

1968N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.28	18.73	[a] ACQUIN [RF]
			[B]4.05	21.33	18.73	[a] Accupril [PF]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

ramipril 10 mg capsule, 30

8470T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.22	18.67	[a] APO-Ramipril [TX] [a] Prilace [RF] [a] Ramipril Winthrop [WA] [a] Tryzan Caps 10 [AF]	[a] APX-Ramipril [TY] [a] Ramipril Sandoz [SZ] [a] Tritace 10 mg [SW]

ramipril 10 mg tablet, 30

1316G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.22	18.67	[a] APO-Ramipril [TX] [a] Tritace [SW]	[a] Ramipril Sandoz [SZ] [a] Tryzan Tabs 10 [AF]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

ramipril 1.25 mg capsule, 30

9120B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] Tryzan Caps 1.25 [AF]

ramipril 1.25 mg tablet, 30

1944H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] Prilace [RF] [a] Ramipril Viatris [AL] [a] Tritace 1.25 mg [SW]	[a] Ramipril Sandoz [SZ] [a] Ramipril Winthrop [WA] [a] Tryzan Tabs 1.25 [AF]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

ramipril 2.5 mg capsule, 30

9121C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] APO-Ramipril [TX]	[a] Tryzan Caps 2.5 [AF]

ramipril 2.5 mg tablet, 30

1945J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] APO-Ramipril [TX] [a] Ramipril Sandoz [SZ] [a] Ramipril Winthrop [WA] [a] Tryzan Tabs 2.5 [AF]	[a] Prilace [RF] [a] Ramipril Viatris [AL] [a] Tritace 2.5 mg [SW]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

ramipril 5 mg capsule, 30

9122D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] APO-Ramipril [TX]	[a] Tryzan Caps 5 [AF]

ramipril 5 mg tablet, 30

1946K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] APO-Ramipril [TX] [a] Ramipril Sandoz [SZ] [a] Tritace 5 mg [SW]	[a] Prilace [RF] [a] Ramipril Winthrop [WA] [a] Tryzan Tabs 5 [AF]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

Restricted benefit

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

ramipril 10 mg capsule, 30

13430W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] APO-Ramipril [TX] [a] Prilace [RF] [a] Ramipril Winthrop [WA] [a] Tryzan Caps 10 [AF]	[a] APX-Ramipril [TY] [a] Ramipril Sandoz [SZ] [a] Tritace 10 mg [SW]

ramipril 10 mg tablet, 30

13368N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] APO-Ramipril [TX] [a] Tritace [SW]	[a] Ramipril Sandoz [SZ] [a] Tryzan Tabs 10 [AF]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

Restricted benefit

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

ramipril 2.5 mg capsule, 30

13405M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] APO-Ramipril [TX]	[a] Tryzan Caps 2.5 [AF]

ramipril 2.5 mg tablet, 30

13466R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] APO-Ramipril [TX] [a] Ramipril Sandoz [SZ] [a] Ramipril Winthrop [WA] [a] Tryzan Tabs 2.5 [AF]	[a] Prilace [RF] [a] Ramipril Viatris [AL] [a] Tritace 2.5 mg [SW]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

Restricted benefit

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

ramipril 1.25 mg capsule, 30

13431X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] Tryzan Caps 1.25 [AF]

ramipril 1.25 mg tablet, 30

13582W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] Prilace [RF] [a] Ramipril Viatris [AL] [a] Tritace 1.25 mg [SW]	[a] Ramipril Sandoz [SZ] [a] Ramipril Winthrop [WA] [a] Tryzan Tabs 1.25 [AF]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

Restricted benefit

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

ramipril 5 mg capsule, 30

13556L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] APO-Ramipril [TX]	[a] Tryzan Caps 5 [AF]

ramipril 5 mg tablet, 30

13526X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] APO-Ramipril [TX] [a] Ramipril Sandoz [SZ]	[a] Prilace [RF] [a] Ramipril Winthrop [WA]

						[a] Tritace 5 mg [SW]	[a] Tryzan Tabs 5 [AF]

▪ TRANDOLAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

trandolapril 2 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2793B							
NP	1	5	..	18.24	19.69	[a] Dolapril 2 [RW]	[a] Tranalpha [AF]
			[B]3.50	21.74	19.69	[a] Gopten [GO]	

trandolapril 4 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8758Y							
NP	1	5	..	22.45	23.90	[a] Dolapril 4 [RW]	[a] Tranalpha [AF]
			[B]3.49	25.94	23.90	[a] Gopten [GO]	

trandolapril 500 microgram capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2791X							
NP	1	5	..	16.17	17.62	[a] Dolapril 0.5 [RW]	[a] Tranalpha [AF]
			[B]3.48	19.65	17.62	[a] Gopten [GO]	

trandolapril 1 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2792Y							
NP	1	5	..	17.43	18.88	[a] Dolapril 1 [RW]	[a] Tranalpha [AF]
			[B]3.50	20.93	18.88	[a] Gopten [GO]	

▪ TRANDOLAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

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

trandolapril 2 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13403K							
NP	2	5	..	*23.03	24.48	[a] Dolapril 2 [RW]	[a] Tranalpha [AF]
			[B]7.00	*30.03	24.48	[a] Gopten [GO]	

trandolapril 4 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13467T							
NP	2	5	..	*31.45	31.60	[a] Dolapril 4 [RW]	[a] Tranalpha [AF]
			[B]6.98	*38.43	31.60	[a] Gopten [GO]	

trandolapril 500 microgram capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13554J							
NP	2	5	..	*18.89	20.34	[a] Dolapril 0.5 [RW]	[a] Tranalpha [AF]
			[B]6.96	*25.85	20.34	[a] Gopten [GO]	

trandolapril 1 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13429T							
NP	2	5	..	*21.41	22.86	[a] Dolapril 1 [RW]	[a] Tranalpha [AF]
			[B]7.00	*28.41	22.86	[a] Gopten [GO]	

ACE INHIBITORS, COMBINATIONS

ACE inhibitors and diuretics

▪ ENALAPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8477E							
NP	1	5	..	18.83	20.28	[a] Enalapril/HCT Sandoz [SZ]	[a] Renitec Plus 20/6 [AF]

▪ ENALAPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30

13439H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*24.21	25.66	[a] Enalapril/HCT Sandoz [SZ]	[a] Renitec Plus 20/6 [AF]

▪ FOSINOPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

8401E

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	21.86	23.31	Fosetic 20/12.5 [ZP]

▪ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30

2190G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] PREXUM Combi LD 2.5/0.625 [RX]
		[B]7.86	24.03	17.62	[a] Coversyl Plus LD 2.5mg/0.625mg [SE]

▪ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

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

perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30

13413Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] PREXUM Combi LD 2.5/0.625 [RX]
		[B]15.72	*34.61	20.34	[a] Coversyl Plus LD 2.5mg/0.625mg [SE]

▪ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

8449Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.22	18.67	[a] APO-Perindopril/Indapamide [TX]	[a] GenRx Perindopril/ Indapamide 4/1.25 [GX]
					[a] Idaprex Combi 4/1.25 [SZ]	[a] Indosyl Combi 4/1.25 [RW]
					[a] Perindo Combi 4/1.25 [AF]	[a] PERISYL COMBI 4/1.25 [AL]

perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

2845R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.22	18.67	[a] Prexum Combi 5/1.25 [RX]
		[B]7.14	24.36	18.67	[a] Coversyl Plus 5mg/1.25mg [SE]

▪ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

13476G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] APO-Perindopril/Indapamide [TX]	[a] GenRx Perindopril/ Indapamide 4/1.25 [GX]
					[a] Idaprex Combi 4/1.25 [SZ]	[a] Indosyl Combi 4/1.25 [RW]
					[a] Perindo Combi 4/1.25 [AF]	[a] PERISYL COMBI 4/1.25 [AL]

perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

13506W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] Prexum Combi 5/1.25 [RX]
		[B]14.28	*35.27	22.44	[a] Coversyl Plus 5mg/1.25mg [SE]

▪ QUINAPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

8589C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	19.04	20.49	Accuretic 10/12.5mg [PF]

quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

8590D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	19.95	21.40	Accuretic 20/12.5mg [PF]

ACE inhibitors and calcium channel blockers

▪ LERCANIDIPINE + ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9144G NP	1	5	..	18.44	19.89	Zan-Extra 10/10 [GO]

lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9145H NP	1	5	..	19.22	20.67	Zan-Extra 10/20 [GO]

▪ LERCANIDIPINE + ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13507X NP	2	5	..	*23.43	24.88	Zan-Extra 10/10 [GO]

lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13477H NP	2	5	..	*24.99	26.44	Zan-Extra 10/20 [GO]

▪ PERINDOPRIL + AMLODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease

Clinical criteria:

- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9349C NP	1	5	..	19.42	20.87	[a] APO-Perindopril Arginine/Amlodipine 10/10 [TX] [a] Reaptan 10/10 [RX]	[a] APX-Perindopril Arginine/Amlodipine 10/10 [XT]
			[B]9.85	29.27	20.87	[a] Coveram 10/10 [SE]	

perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9348B NP	1	5	..	18.73	20.18	[a] APO-Perindopril Arginine/Amlodipine 10/5 [TX] [a] Reaptan 10/5 [RX]	[a] APX-Perindopril Arginine/Amlodipine 10/5 [XT]
			[B]9.54	28.27	20.18	[a] Coveram 10/5 [SE]	

perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9347Y NP	1	5	..	17.90	19.35	[a] APO-Perindopril Arginine/Amlodipine 5/10 [TX] [a] Reaptan 5/10 [RX]	[a] APX-Perindopril Arginine/Amlodipine 5/10 [XT]
			[B]9.39	27.29	19.35	[a] Coveram 5/10 [SE]	

perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9346X NP	1	5	..	17.22	18.67	[a] APO-Perindopril Arginine/Amlodipine 5/5 [TX] [a] Reaptan 5/5 [RX]	[a] APX-Perindopril Arginine/Amlodipine 5/5 [XT]

[B]9.08	26.30	18.67	[a] Coveram 5/5 [SE]	

▪ PERINDOPRIL + AMLODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

13382H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*25.39	26.84	[a] APO-Perindopril Arginine/Amlodipine 10/10 [TX] [a] Reaptan 10/10 [RX]	[a] APX-Perindopril Arginine/Amlodipine 10/10 [XT]
		[B]19.70	*45.09	26.84	[a] Coveram 10/10 [SE]	

perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

13478J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*24.01	25.46	[a] APO-Perindopril Arginine/Amlodipine 10/5 [TX] [a] Reaptan 10/5 [RX]	[a] APX-Perindopril Arginine/Amlodipine 10/5 [XT]
		[B]19.08	*43.09	25.46	[a] Coveram 10/5 [SE]	

perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

13381G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.35	23.80	[a] APO-Perindopril Arginine/Amlodipine 5/10 [TX] [a] Reaptan 5/10 [RX]	[a] APX-Perindopril Arginine/Amlodipine 5/10 [XT]
		[B]18.78	*41.13	23.80	[a] Coveram 5/10 [SE]	

perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

13508Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] APO-Perindopril Arginine/Amlodipine 5/5 [TX] [a] Reaptan 5/5 [RX]	[a] APX-Perindopril Arginine/Amlodipine 5/5 [XT]
		[B]18.16	*39.15	22.44	[a] Coveram 5/5 [SE]	

▪ RAMIPRIL + FELODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30

2626F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.76	19.21	Triasyn 2.5/2.5 [SW]

ramipril 5 mg + felodipine 5 mg modified release tablet, 30

2629J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	19.36	20.81	Triasyn 5.0/5.0 [SW]

▪ RAMIPRIL + FELODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30

13563W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*22.07	23.52	Triasyn 2.5/2.5 [SW]

ramipril 5 mg + felodipine 5 mg modified release tablet, 30

13534H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*25.27	26.72	Triasyn 5.0/5.0 [SW]

▪ TRANDOLAPRIL + VERAPAMIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28

9387C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	23.88	25.33	Tarka 2/180 [GO]

trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28

2857J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	29.95	31.40	Tarka 4/240 [GO]

▪ TRANDOLAPRIL + VERAPAMIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28

13594L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*34.31	31.60	Tarka 2/180 [GO]

trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28

13591H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*46.45	31.60	Tarka 4/240 [GO]

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

Angiotensin II receptor blockers (ARBs), plain

▪ CANDESARTAN

candesartan cilexetil 16 mg tablet, 30

8297Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.59	19.04	[a] Adesan [AF]	[a] APO-Candesartan [TX]
					[a] Blooms the Chemist Candesartan [IB]	[a] BTC Candesartan [BG]
					[a] CANDESAN [RF]	[a] Candesartan Sandoz [SZ]
		[B]13.47	31.06	19.04	[a] Atacand [LM]	

candesartan cilexetil 32 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8889W NP	1	5	..	17.76	19.21	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]11.61	29.37	19.21	[a] Atacand [LM]	

candesartan cilexetil 4 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8295N NP	1	5	..	16.17	17.62	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]13.45	29.62	17.62	[a] Atacand [LM]	

candesartan cilexetil 8 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8296P NP	1	5	..	16.17	17.62	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]13.45	29.62	17.62	[a] Atacand [LM]	

▪ CANDESARTAN

Restricted benefit

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

candesartan cilexetil 16 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13565Y NP	2	5	..	*21.73	23.18	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]26.94	*48.67	23.18	[a] Atacand [LM]	

candesartan cilexetil 32 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13438G NP	2	5	..	*22.07	23.52	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]23.22	*45.29	23.52	[a] Atacand [LM]	

candesartan cilexetil 4 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13592J NP	2	5	..	*18.89	20.34	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]26.90	*45.79	20.34	[a] Atacand [LM]	

candesartan cilexetil 8 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13436E NP	2	5	..	*18.89	20.34	[a] Adesan [AF] [a] Blooms the Chemist Candesartan [IB] [a] CANDESAN [RF]	[a] APO-Candesartan [TX] [a] BTC Candesartan [BG] [a] Candesartan Sandoz [SZ]
			[B]26.90	*45.79	20.34	[a] Atacand [LM]	

▪ EPROSARTAN

eprosartan 600 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8447N NP	1	5	[T]2.62	27.74	26.57	Teveten [GO]

▪ EPROSARTAN

Restricted benefit

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

eprosartan 600 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13912F NP	2	5	[T]5.24	*42.03	31.60	Teveten [GO]

▪ EPROSARTAN

Authority required

Adverse effects occurring with all of the base-priced drugs

Authority required

Drug interactions occurring with all of the base-priced drugs

Authority required

Drug interactions expected to occur with all of the base-priced drugs

Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

eprosartan 600 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5491B NP	1	5	..	27.74	29.19	Teveten [GO]

▪ EPROSARTAN

Authority required

Adverse effects occurring with all of the base-priced drugs

Clinical criteria:

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

Authority required

Drug interactions occurring with all of the base-priced drugs

Clinical criteria:

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

Authority required

Drug interactions expected to occur with all of the base-priced drugs

Clinical criteria:

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

Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

Clinical criteria:

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

eprosartan 600 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13861M NP	2	5	..	*42.03	31.60	Teveten [GO]

▪ IRBESARTAN

irbesartan 150 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8247C NP	1	5	..	16.17	17.62	[a] Abisart 150 [AL]	[a] APO-Irbesartan [TX]
						[a] AVSARTAN [RF]	[a] Blooms Irbesartan [BG]
						[a] Blooms the Chemist Irbesartan [IB]	[a] Irbesartan GH [GQ]
						[a] Irbesartan Sandoz [SZ]	[a] Noumed Irbesartan [VO]
			[B]3.50	19.67	17.62	[a] Avapro [AV]	[a] Karvea [SW]

irbesartan 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8248D NP	1	5	..	17.22	18.67	[a] Abisart 300 [AL]	[a] APO-Irbesartan [TX]
						[a] AVSARTAN [RF]	[a] Blooms Irbesartan [BG]
						[a] Blooms the Chemist Irbesartan [IB]	[a] Irbesartan GH [GQ]
						[a] Irbesartan Sandoz [SZ]	[a] Noumed Irbesartan [VO]
			[B]3.50	20.72	18.67	[a] Avapro [AV]	[a] Karvea [SW]

irbesartan 75 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8246B NP	1	5	..	16.17	17.62	[a] Abisart 75 [AL]	[a] APO-Irbesartan [TX]
						[a] AVSARTAN [RF]	[a] Blooms Irbesartan [BG]

						[a] Blooms the Chemist Irbesartan [IB]	[a] Irbesartan GH [GQ]
						[a] Irbesartan Sandoz [SZ]	[a] Noumed Irbesartan [VO]
			[B]3.10	19.27	17.62	[a] Avapro [AV]	[a] Karvea [SW]

▪ IRBESARTAN

Restricted benefit

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

irbesartan 150 mg tablet, 30

13380F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Abisart 150 [AL]	[a] APO-Irbesartan [TX]
						[a] AVSARTAN [RF]	[a] Blooms Irbesartan [BG]
						[a] Blooms the Chemist Irbesartan [IB]	[a] Irbesartan GH [GQ]
						[a] Irbesartan Sandoz [SZ]	[a] Noumed Irbesartan [VO]
			[B]7.00	*25.89	20.34	[a] Avapro [AV]	[a] Karvea [SW]

irbesartan 300 mg tablet, 30

13564X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	[a] Abisart 300 [AL]	[a] APO-Irbesartan [TX]
						[a] AVSARTAN [RF]	[a] Blooms Irbesartan [BG]
						[a] Blooms the Chemist Irbesartan [IB]	[a] Irbesartan GH [GQ]
						[a] Irbesartan Sandoz [SZ]	[a] Noumed Irbesartan [VO]
			[B]7.00	*27.99	22.44	[a] Avapro [AV]	[a] Karvea [SW]

irbesartan 75 mg tablet, 30

13435D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Abisart 75 [AL]	[a] APO-Irbesartan [TX]
						[a] AVSARTAN [RF]	[a] Blooms Irbesartan [BG]
						[a] Blooms the Chemist Irbesartan [IB]	[a] Irbesartan GH [GQ]
						[a] Irbesartan Sandoz [SZ]	[a] Noumed Irbesartan [VO]
			[B]6.20	*25.09	20.34	[a] Avapro [AV]	[a] Karvea [SW]

▪ OLMESARTAN

olmesartan medoxomil 20 mg tablet, 30

2147B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.58	19.03	[a] APO-Olmesartan [TX]	[a] APX-Olmesartan [TY]
						[a] Blooms The Chemist Olmesartan [BG]	[a] OLMERTAN [RW]
						[a] Olmesartan - MYL [AF]	[a] Olmesartan Sandoz [SZ]
						[a] Olsetan [MQ]	[a] Pharmacor Olmesartan 20 [CR]
			[B]3.50	21.08	19.03	[a] Olmetec [AL]	

olmesartan medoxomil 40 mg tablet, 30

2148C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.56	21.01	[a] APO-Olmesartan [TX]	[a] APX-Olmesartan [TY]
						[a] Blooms The Chemist Olmesartan [BG]	[a] OLMERTAN [RW]
						[a] Olmesartan - MYL [AF]	[a] Olmesartan Sandoz [SZ]
						[a] Olsetan [MQ]	[a] Pharmacor Olmesartan 40 [CR]
			[B]2.45	22.01	21.01	[a] Olmetec [AL]	

▪ OLMESARTAN

Restricted benefit

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

olmesartan medoxomil 20 mg tablet, 30

13505T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.71	23.16	[a] APO-Olmesartan [TX]	[a] APX-Olmesartan [TY]
						[a] Blooms The Chemist Olmesartan [BG]	[a] OLMERTAN [RW]
						[a] Olmesartan - MYL [AF]	[a] Olmesartan Sandoz [SZ]
						[a] Olsetan [MQ]	[a] Pharmacor Olmesartan 20 [CR]
			[B]7.00	*28.71	23.16	[a] Olmetec [AL]	

olmesartan medoxomil 40 mg tablet, 30

13533G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.67	27.12	[a] APO-Olmesartan [TX] [a] Blooms The Chemist Olmesartan [BG] [a] Olmesartan - MYL [AF] [a] Olsetan [MQ]	[a] APX-Olmesartan [TY] [a] OLMERTAN [RW] [a] Olmesartan Sandoz [SZ] [a] Pharmacor Olmesartan 40 [CR]
			[B]4.90	*30.57	27.12	[a] Olmetec [AL]	

▪ TELMISARTAN

telmisartan 40 mg tablet, 28

8355R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	[a] APO-Telmisartan [TX] [a] NOUMED TELMISARTAN [VO] [a] Telmisartan Sandoz [SZ]	[a] Mizart [AF] [a] Pharmacor Telmisartan 40 [CR] [a] Teltartan [RW]
			[B]5.58	21.75	17.62	[a] Micardis [BY]	

telmisartan 80 mg tablet, 28

8356T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	[a] APO-Telmisartan [TX] [a] NOUMED TELMISARTAN [VO] [a] Telmisartan Sandoz [SZ]	[a] Mizart [AF] [a] Pharmacor Telmisartan 80 [CR] [a] Teltartan [RW]
			[B]4.48	22.24	19.21	[a] Micardis [BY]	

▪ TELMISARTAN

Restricted benefit

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

telmisartan 40 mg tablet, 28

13437F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] APO-Telmisartan [TX] [a] NOUMED TELMISARTAN [VO] [a] Telmisartan Sandoz [SZ]	[a] Mizart [AF] [a] Pharmacor Telmisartan 40 [CR] [a] Teltartan [RW]
			[B]11.16	*30.05	20.34	[a] Micardis [BY]	

telmisartan 80 mg tablet, 28

13593K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	[a] APO-Telmisartan [TX] [a] NOUMED TELMISARTAN [VO] [a] Telmisartan Sandoz [SZ]	[a] Mizart [AF] [a] Pharmacor Telmisartan 80 [CR] [a] Teltartan [RW]
			[B]8.96	*31.03	23.52	[a] Micardis [BY]	

▪ VALSARTAN

valsartan 160 mg tablet, 28

9370E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.49	22.94	[a] Dilart [AF]	[a] Diovan [NV]

valsartan 40 mg tablet, 28

9368C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.43	19.88	[a] Dilart [AF]	[a] Diovan [NV]

valsartan 80 mg tablet, 28

9369D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.72	21.17	[a] Dilart [AF]	[a] Diovan [NV]

▪ VALSARTAN

Note No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

valsartan 320 mg tablet, 28

9371F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.76	25.21	[a] Dilart [AF]	[a] Diovan [NV]

▪ VALSARTAN

Restricted benefit

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

valsartan 160 mg tablet, 28

13566B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*29.53	30.98	[a] Dilart [AF]	[a] Diovan [NV]

valsartan 80 mg tablet, 28

13414B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*25.99	27.44	[a] Dilart [AF]	[a] Diovan [NV]

▪ VALSARTAN

Note No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

Restricted benefit

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

valsartan 320 mg tablet, 28

13383J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*34.07	31.60	[a] Dilart [AF]	[a] Diovan [NV]

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

Angiotensin II receptor blockers (ARBs) and diuretics

▪ CANDESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

8504N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] Adesan HCT 16/12.5 [AF]	[a] APO-Candesartan HCTZ 16/12.5 [TX]
					[a] Blooms the Chemist Candesartan HCTZ 16/12.5 [IB]	[a] BTC Candesartan HCT [BG]
					[a] CANDESAN COMBI 16/12.5 [RF]	[a] Candesartan/HCT Sandoz [SZ]
					[a] NOUMED CANDESARTAN/HCT [VO]	
		[B]13.09	30.85	19.21	[a] Atacand Plus 16/12.5 [LM]	

candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9314F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] Adesan HCT 32/12.5 [AF]	[a] APO-Candesartan HCTZ 32/12.5 [TX]
					[a] Blooms the Chemist Candesartan HCTZ 32/12.5 [IB]	[a] BTC Candesartan HCT [BG]
					[a] CANDESAN COMBI 32/12.5 [RF]	[a] Candesartan/HCT Sandoz [SZ]
					[a] NOUMED CANDESARTAN/HCT [VO]	
		[B]11.18	28.94	19.21	[a] Atacand Plus 32/12.5 [LM]	

candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

9315G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.30	19.75	[a] Adesan HCT 32/25 [AF]	[a] APO-Candesartan HCTZ 32/25 [TX]
					[a] Blooms the Chemist Candesartan HCTZ 32/25 [IB]	[a] BTC Candesartan HCT [BG]
					[a] CANDESAN COMBI 32/25 [RF]	[a] Candesartan/HCT Sandoz [SZ]
					[a] NOUMED CANDESARTAN/HCT [VO]	
		[B]10.85	29.15	19.75	[a] Atacand Plus 32/25 [LM]	

▪ CANDESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

13391T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] Adesan HCT 16/12.5 [AF]	[a] APO-Candesartan HCTZ 16/12.5 [TX]
					[a] Blooms the Chemist Candesartan HCTZ 16/12.5 [IB]	[a] BTC Candesartan HCT [BG]
					[a] CANDESAN COMBI 16/12.5 [RF]	[a] Candesartan/HCT Sandoz [SZ]
					[a] NOUMED CANDESARTAN/HCT [VO]	
		[B]26.18	*48.25	23.52	[a] Atacand Plus 16/12.5 [LM]	

candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

13452B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] Adesan HCT 32/12.5 [AF]	[a] APO-Candesartan HCTZ 32/12.5 [TX]
					[a] Blooms the Chemist Candesartan HCTZ 32/12.5 [IB]	[a] BTC Candesartan HCT [BG]
					[a] CANDESAN COMBI 32/12.5 [RF]	[a] Candesartan/HCT Sandoz [SZ]
					[a] NOUMED CANDESARTAN/HCT [VO]	
		[B]22.36	*44.43	23.52	[a] Atacand Plus 32/12.5 [LM]	

candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

13392W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*23.15	24.60	[a] Adesan HCT 32/25 [AF]	[a] APO-Candesartan HCTZ 32/25 [TX]
					[a] Blooms the Chemist Candesartan HCTZ 32/25 [IB]	[a] BTC Candesartan HCT [BG]
					[a] CANDESAN COMBI 32/25 [RF]	[a] Candesartan/HCT Sandoz [SZ]
					[a] NOUMED CANDESARTAN/HCT [VO]	
		[B]21.70	*44.85	24.60	[a] Atacand Plus 32/25 [LM]	

▪ EPROSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

8624X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	26.25	27.70	Teveten Plus 600/12.5 [GO]

▪ IRBESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8404H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] Abisart HCTZ 150/12.5 [AL]	[a] APO-Irbesartan HCTZ [TX]
					[a] AVSARTAN HCT 150/12.5 [RF]	[a] Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB]
					[a] Irbesartan/HCT Sandoz [SZ]	

			[B]3.50	19.67	17.62	[a] Avapro HCT 150/12.5 [AV]	[a] Karvezide 150/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.33	18.78	[a] Abisart HCTZ 300/12.5 [AL] [a] AVSARTAN HCT 300/12.5 [RF] [a] Irbesartan/HCT Sandoz [SZ]	[a] APO-Irbesartan HCTZ [TX] [a] Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB]
			[B]3.50	20.83	18.78	[a] Avapro HCT 300/12.5 [AV]	[a] Karvezide 300/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

2136K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.67	19.12	[a] Abisart HCTZ 300/25 [AL] [a] AVSARTAN HCT 300/25 [RF] [a] Irbesartan/HCT Sandoz [SZ]	[a] APO-Irbesartan HCTZ [TX] [a] Blooms the Chemist Irbesartan HCTZ 300/25 [IB]
			[B]3.50	21.17	19.12	[a] Avapro HCT 300/25 [AV]	[a] Karvezide 300/25 [SW]

▪ IRBESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

13572H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Abisart HCTZ 150/12.5 [AL] [a] AVSARTAN HCT 150/12.5 [RF] [a] Irbesartan/HCT Sandoz [SZ]	[a] APO-Irbesartan HCTZ [TX] [a] Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB]
			[B]7.00	*25.89	20.34	[a] Avapro HCT 150/12.5 [AV]	[a] Karvezide 150/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

13545X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.21	22.66	[a] Abisart HCTZ 300/12.5 [AL] [a] AVSARTAN HCT 300/12.5 [RF] [a] Irbesartan/HCT Sandoz [SZ]	[a] APO-Irbesartan HCTZ [TX] [a] Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB]
			[B]7.00	*28.21	22.66	[a] Avapro HCT 300/12.5 [AV]	[a] Karvezide 300/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

13446Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.89	23.34	[a] Abisart HCTZ 300/25 [AL] [a] AVSARTAN HCT 300/25 [RF] [a] Irbesartan/HCT Sandoz [SZ]	[a] APO-Irbesartan HCTZ [TX] [a] Blooms the Chemist Irbesartan HCTZ 300/25 [IB]
			[B]7.00	*28.89	23.34	[a] Avapro HCT 300/25 [AV]	[a] Karvezide 300/25 [SW]

▪ OLMESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

2161R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	[a] APO-Olmesartan/HCTZ 20/12.5 [TX] [a] OLMERTAN COMBI 20/12.5 [RW] [a] Olmesartan/HCT Sandoz [SZ]	[a] APX-Olmesartan/HCTZ [TY] [a] Olmesartan HCT - MYL 20/12.5 [AF] [a] Pharmacor Olmesartan HCTZ 20/12.5 [CR]
			[B]3.00	20.76	19.21	[a] Olmetec Plus [AL]	

olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2166B NP	1	5	..	19.36	20.81	[a] APO-Olmesartan/HCTZ 40/12.5 [TX]	[a] APX-Olmesartan/HCTZ [TY]
						[a] OLMERTAN COMBI 40/12.5 [RW]	[a] Olmesartan HCT - MYL 40/12.5 [AF]
						[a] Olmesartan/HCT Sandoz [SZ]	[a] Pharmacor Olmesartan HCTZ 40/12.5 [CR]
			[B]3.25	22.61	20.81	[a] Olmetec Plus [AL]	

olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2170F NP	1	5	..	20.13	21.58	[a] APO-Olmesartan/HCTZ 40/25 [TX]	[a] APX-Olmesartan/HCTZ [TY]
						[a] OLMERTAN COMBI 40/25 [RW]	[a] Olmesartan HCT - MYL 40/25 [AF]
						[a] Olmesartan/HCT Sandoz [SZ]	[a] Pharmacor Olmesartan HCTZ 40/25 [CR]
			[B]2.26	22.39	21.58	[a] Olmetec Plus [AL]	

▪ OLMESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13447R NP	2	5	..	*22.07	23.52	[a] APO-Olmesartan/HCTZ 20/12.5 [TX]	[a] APX-Olmesartan/HCTZ [TY]
						[a] OLMERTAN COMBI 20/12.5 [RW]	[a] Olmesartan HCT - MYL 20/12.5 [AF]
						[a] Olmesartan/HCT Sandoz [SZ]	[a] Pharmacor Olmesartan HCTZ 20/12.5 [CR]
			[B]6.00	*28.07	23.52	[a] Olmetec Plus [AL]	

olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13601W NP	2	5	..	*25.27	26.72	[a] APO-Olmesartan/HCTZ 40/12.5 [TX]	[a] APX-Olmesartan/HCTZ [TY]
						[a] OLMERTAN COMBI 40/12.5 [RW]	[a] Olmesartan HCT - MYL 40/12.5 [AF]
						[a] Olmesartan/HCT Sandoz [SZ]	[a] Pharmacor Olmesartan HCTZ 40/12.5 [CR]
			[B]6.50	*31.77	26.72	[a] Olmetec Plus [AL]	

olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13602X NP	2	5	..	*26.81	28.26	[a] APO-Olmesartan/HCTZ 40/25 [TX]	[a] APX-Olmesartan/HCTZ [TY]
						[a] OLMERTAN COMBI 40/25 [RW]	[a] Olmesartan HCT - MYL 40/25 [AF]
						[a] Olmesartan/HCT Sandoz [SZ]	[a] Pharmacor Olmesartan HCTZ 40/25 [CR]
			[B]4.52	*31.33	28.26	[a] Olmetec Plus [AL]	

▪ TELMISARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8622T NP	1	5	..	16.29	17.74	[a] APO-Telmisartan HCTZ 40/12.5 [TX]	[a] Mizart HCT 40/12.5 mg [AF]

						[a] Telmisartan/HCT Sandoz [SZ]	[a] Teltartan HCT 40/12.5 [RW]
			[B]5.54	21.83	17.74	[a] Micardis Plus 40/12.5 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

8623W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	[a] APO-Telmisartan HCTZ 80/12.5 [TX]	[a] Mizart HCT 80/12.5 mg [AF]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Teltartan HCT 80/12.5 [RW]
			[B]4.01	21.77	19.21	[a] Micardis Plus 80/12.5 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

9381R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.09	19.54	[a] APO-Telmisartan HCTZ 80/25 [TX]	[a] Mizart HCT 80/25 mg [AF]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Teltartan HCT 80/25 [RW]
			[B]3.97	22.06	19.54	[a] Micardis Plus 80/25 mg [BY]	

▪ TELMISARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

13546Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.13	20.58	[a] APO-Telmisartan HCTZ 40/12.5 [TX]	[a] Mizart HCT 40/12.5 mg [AF]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Teltartan HCT 40/12.5 [RW]
			[B]11.08	*30.21	20.58	[a] Micardis Plus 40/12.5 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

13574K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	[a] APO-Telmisartan HCTZ 80/12.5 [TX]	[a] Mizart HCT 80/12.5 mg [AF]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Teltartan HCT 80/12.5 [RW]
			[B]8.02	*30.09	23.52	[a] Micardis Plus 80/12.5 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

13607E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.73	24.18	[a] APO-Telmisartan HCTZ 80/25 [TX]	[a] Mizart HCT 80/25 mg [AF]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Teltartan HCT 80/25 [RW]
			[B]7.94	*30.67	24.18	[a] Micardis Plus 80/25 mg [BY]	

▪ VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

9373H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.71	23.16	[a] Co-Diovan 160/12.5 [NV]	[a] Dilart HCT 160/12.5 [AF]

valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

9374J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.81	24.26	[a] Co-Diovan 160/25 [NV]	[a] Dilart HCT 160/25 [AF]

valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

9372G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.13	21.58	[a] Co-Diovan 80/12.5 [NV]	[a] Dilart HCT 80/12.5 [AF]

▪ VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13606D NP	2	5	..	*29.97	31.42	[a] Co-Diovan 160/12.5 [NV]	[a] Dilart HCT 160/12.5 [AF]

valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13453C NP	2	5	..	*32.17	31.60	[a] Co-Diovan 160/25 [NV]	[a] Dilart HCT 160/25 [AF]

valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13393X NP	2	5	..	*26.81	28.26	[a] Co-Diovan 80/12.5 [NV]	[a] Dilart HCT 80/12.5 [AF]

▪ VALSARTAN + HYDROCHLOROTHIAZIDE

Note No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9481B NP	1	5	..	23.73	25.18	[a] Co-Diovan 320/12.5 [NV]	[a] Dilart HCT 320/12.5 [AF]

valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9482C NP	1	5	..	24.82	26.27	[a] Co-Diovan 320/25 [NV]	[a] Dilart HCT 320/25 [AF]

▪ VALSARTAN + HYDROCHLOROTHIAZIDE

Note No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13517K NP	2	5	..	*34.01	31.60	[a] Co-Diovan 320/12.5 [NV]	[a] Dilart HCT 320/12.5 [AF]

valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13455E NP	2	5	..	*36.19	31.60	[a] Co-Diovan 320/25 [NV]	[a] Dilart HCT 320/25 [AF]

Angiotensin II receptor blockers (ARBs) and calcium channel blockers

▪ AMLODIPINE + VALSARTAN

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

amlodipine 5 mg + valsartan 320 mg tablet, 28

5459H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	26.06	27.51	[a] Amlodipine/Valsartan Novartis 5/320 [NM]
			[B]4.00	30.06	27.51	[a] Exforge 5/320 [NV]

amlodipine 5 mg + valsartan 80 mg tablet, 28

9375K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	21.44	22.89	[a] Amlodipine/Valsartan Novartis 5/80 [NM]
			[B]4.00	25.44	22.89	[a] Exforge 5/80 [NV]

amlodipine 10 mg + valsartan 160 mg tablet, 28

9377M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	24.00	25.45	[a] Amlodipine/Valsartan Novartis 10/160 [NM]
			[B]4.00	28.00	25.45	[a] Exforge 10/160 [NV]

amlodipine 10 mg + valsartan 320 mg tablet, 28

5460J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	26.27	27.72	[a] Amlodipine/Valsartan Novartis 10/320 [NM]
			[B]4.00	30.27	27.72	[a] Exforge 10/320 [NV]

amlodipine 5 mg + valsartan 160 mg tablet, 28

9376L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	23.47	24.92	[a] Amlodipine/Valsartan Novartis 5/160 [NM]
			[B]4.00	27.47	24.92	[a] Exforge 5/160 [NV]

▪ AMLODIPINE + VALSARTAN

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

amlodipine 5 mg + valsartan 320 mg tablet, 28

13604B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*38.67	31.60	[a] Amlodipine/Valsartan Novartis 5/320 [NM]
			[B]8.00	*46.67	31.60	[a] Exforge 5/320 [NV]

amlodipine 5 mg + valsartan 80 mg tablet, 28

13421J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*29.43	30.88	[a] Amlodipine/Valsartan Novartis 5/80 [NM]
			[B]8.00	*37.43	30.88	[a] Exforge 5/80 [NV]

amlodipine 10 mg + valsartan 160 mg tablet, 28

13454D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*34.55	31.60	[a] Amlodipine/Valsartan Novartis 10/160 [NM]
			[B]8.00	*42.55	31.60	[a] Exforge 10/160 [NV]

amlodipine 10 mg + valsartan 320 mg tablet, 28

13389Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*39.09	31.60	[a] Amlodipine/Valsartan Novartis 10/320 [NM]
			[B]8.00	*47.09	31.60	[a] Exforge 10/320 [NV]

amlodipine 5 mg + valsartan 160 mg tablet, 28

13516J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*33.49	31.60	[a] Amlodipine/Valsartan Novartis 5/160 [NM]
			[B]8.00	*41.49	31.60	[a] Exforge 5/160 [NV]

▪ OLMESARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5292M NP	1	5	..	17.35	18.80	[a] OLMEKAR [RW]	[a] Olmesartan/Amlodipine 20/5 APOTEX [TX]
						[a] Olmesartan/Amlodipine - MYL 20/5 [AF]	[a] Olmesartan/Amlodipine Sandoz [SZ]
						[a] Pharmacor Olmesartan Amlodipine 20/5 [CR]	
			[B]3.00	20.35	18.80	[a] Sevikar 20/5 [AL]	

olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5294P NP	1	5	..	20.33	21.78	[a] OLMEKAR [RW]	[a] Olmesartan/Amlodipine 40/10 APOTEX [TX]
						[a] Olmesartan/Amlodipine - MYL 40/10 [AF]	[a] Olmesartan/Amlodipine Sandoz [SZ]
						[a] Pharmacor Olmesartan Amlodipine 40/10 [CR]	
			[B]3.00	23.33	21.78	[a] Sevikar 40/10 [AL]	

olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5293N NP	1	5	..	19.87	21.32	[a] OLMEKAR [RW]	[a] Olmesartan/Amlodipine 40/5 APOTEX [TX]
						[a] Olmesartan/Amlodipine - MYL 40/5 [AF]	[a] Olmesartan/Amlodipine Sandoz [SZ]
						[a] Pharmacor Olmesartan Amlodipine 40/5 [CR]	
			[B]3.00	22.87	21.32	[a] Sevikar 40/5 [AL]	

▪ OLMESARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13449W NP	2	5	..	*21.25	22.70	[a] OLMEKAR [RW]	[a] Olmesartan/Amlodipine 20/5 APOTEX [TX]
						[a] Olmesartan/Amlodipine - MYL 20/5 [AF]	[a] Olmesartan/Amlodipine Sandoz [SZ]
						[a] Pharmacor Olmesartan Amlodipine 20/5 [CR]	
			[B]6.00	*27.25	22.70	[a] Sevikar 20/5 [AL]	

▪ OLMESARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13943W NP	2	5	..	*27.21	28.66	[a] OLMEKAR [RW]	[a] Olmesartan/Amlodipine 40/10 APOTEX [TX]
						[a] Olmesartan/Amlodipine - MYL 40/10 [AF]	[a] Olmesartan/Amlodipine Sandoz [SZ]

						[a] Pharmacor Olmesartan Amlodipine 40/10 [CR]	
			[B]6.00	*33.21	28.66	[a] Sevikar 40/10 [AL]	

olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

13964Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*26.29	27.74	[a] OLMEKAR [RW]	[a] Olmesartan/Amlodipine 40/5 APOTEX [TX]
						[a] Olmesartan/Amlodipine - MYL 40/5 [AF]	[a] Olmesartan/Amlodipine Sandoz [SZ]
						[a] Pharmacor Olmesartan Amlodipine 40/5 [CR]	
			[B]6.00	*32.29	27.74	[a] Sevikar 40/5 [AL]	

▪ TELMISARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

telmisartan 80 mg + amlodipine 5 mg tablet, 28

8980P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	19.43	20.88	[a] Pritor/Amlodipine [FI]
			[B]5.30	24.73	20.88	[a] Twynsta [BY]

telmisartan 40 mg + amlodipine 10 mg tablet, 28

8979N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	[a] Pritor/Amlodipine [FI]
			[B]5.49	22.71	18.67	[a] Twynsta [BY]

telmisartan 40 mg + amlodipine 5 mg tablet, 28

8978M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	16.60	18.05	[a] Pritor/Amlodipine [FI]
			[B]5.53	22.13	18.05	[a] Twynsta [BY]

telmisartan 80 mg + amlodipine 10 mg tablet, 28

8981Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	20.07	21.52	[a] Pritor/Amlodipine [FI]
			[B]5.30	25.37	21.52	[a] Twynsta [BY]

▪ TELMISARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

telmisartan 80 mg + amlodipine 5 mg tablet, 28

13450X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*25.41	26.86	[a] Pritor/Amlodipine [FI]
			[B]10.60	*36.01	26.86	[a] Twynsta [BY]

telmisartan 40 mg + amlodipine 10 mg tablet, 28

13515H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	[a] Pritor/Amlodipine [FI]
			[B]10.98	*31.97	22.44	[a] Twynsta [BY]

telmisartan 40 mg + amlodipine 5 mg tablet, 28

13483P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*19.75	21.20	[a] Pritor/Amlodipine [FI]
			[B]11.06	*30.81	21.20	[a] Twynsta [BY]

telmisartan 80 mg + amlodipine 10 mg tablet, 28

13451Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*26.69	28.14	[a] Pritor/Amlodipine [FI]
			[B]10.60	*37.29	28.14	[a] Twynsta [BY]

Angiotensin II receptor blockers (ARBs), other combinations

▪ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5287G NP	1	5	..	25.51	26.96	[a] Amlodipine/Valsartan/HCT Novartis 10/160/12.5 [NM]
			[B]4.00	29.51	26.96	[a] Exforge HCT 10/160/12.5 [NV]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5288H NP	1	5	..	27.03	28.48	[a] Amlodipine/Valsartan/HCT Novartis 10/160/25 [NM]
			[B]10.00	37.03	28.48	[a] Exforge HCT 10/160/25 [NV]

amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5289J NP	1	5	..	29.30	30.75	[a] Amlodipine/Valsartan/HCT Novartis 10/320/25 [NM]
			[B]4.00	33.30	30.75	[a] Exforge HCT 10/320/25 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5285E NP	1	5	..	24.99	26.44	[a] Amlodipine/Valsartan/HCT Novartis 5/160/12.5 [NM]
			[B]10.00	34.99	26.44	[a] Exforge HCT 5/160/12.5 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5286F NP	1	5	..	26.50	27.95	[a] Amlodipine/Valsartan/HCT Novartis 5/160/25 [NM]
			[B]4.00	30.50	27.95	[a] Exforge HCT 5/160/25 [NV]

▪ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13514G NP	2	5	..	*37.57	31.60	[a] Amlodipine/Valsartan/HCT Novartis 10/160/12.5 [NM]
			[B]8.00	*45.57	31.60	[a] Exforge HCT 10/160/12.5 [NV]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13390R NP	2	5	..	*40.61	31.60	[a] Amlodipine/Valsartan/HCT Novartis 10/160/25 [NM]
			[B]20.00	*60.61	31.60	[a] Exforge HCT 10/160/25 [NV]

amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13573J NP	2	5	..	*45.15	31.60	[a] Amlodipine/Valsartan/HCT Novartis 10/320/25 [NM]
			[B]8.00	*53.15	31.60	[a] Exforge HCT 10/320/25 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13448T NP	2	5	..	*36.53	31.60	[a] Amlodipine/Valsartan/HCT Novartis 5/160/12.5 [NM]
			[B]20.00	*56.53	31.60	[a] Exforge HCT 5/160/12.5 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13603Y NP	2	5	..	*39.55	31.60	[a] Amlodipine/Valsartan/HCT Novartis 5/160/25 [NM]
			[B]8.00	*47.55	31.60	[a] Exforge HCT 5/160/25 [NV]

▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10005N NP	1	5	..	19.45	20.90	[a] APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX]	[a] Olamlo HCT 20/5/12.5 [AL]
						[a] Olmekar HCT 20/5/12.5 [RF]	[a] Sevikar HCT 20/5/12.5 [AF]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2880N NP	1	5	..	22.29	23.74	[a] APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX]	[a] Olamlo HCT 40/5/12.5 [AL]
						[a] Olmekar HCT 40/5/12.5 [RF]	
			[B]2.62	24.91	23.74	[a] Sevikar HCT 40/5/12.5 [AF]	

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2836G NP	1	5	..	22.70	24.15	[a] APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX]	[a] Olamlo HCT 40/10/12.5 [AL]
						[a] Olmekar HCT 40/10/12.5 [RF]	
			[B]4.26	26.96	24.15	[a] Sevikar HCT 40/10/12.5 [AF]	

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2864R NP	1	5	..	23.85	25.30	[a] APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX]	[a] Olamlo HCT 40/5/25 [AL]
						[a] Olmekar HCT 40/5/25 [RF]	
			[B]2.67	26.52	25.30	[a] Sevikar HCT 40/5/25 [AF]	

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2953K NP	1	5	..	24.23	25.68	[a] APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX]	[a] Olamlo HCT 40/10/25 [AL]
						[a] Olmekar HCT 40/10/25 [RF]	
			[B]2.67	26.90	25.68	[a] Sevikar HCT 40/10/25 [AF]	

▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13481M NP	2	5	..	*25.45	26.90	[a] APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX]	[a] Olamlo HCT 20/5/12.5 [AL]
						[a] Olmekar HCT 20/5/12.5 [RF]	[a] Sevikar HCT 20/5/12.5 [AF]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13513F NP	2	5	..	*31.13	31.60	[a] APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX] [a] Olmekar HCT 40/5/12.5 [RF]	[a] Olamlo HCT 40/5/12.5 [AL]
			[B]5.24	*36.37	31.60	[a] Sevikar HCT 40/5/12.5 [AF]	

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13482N NP	2	5	..	*31.95	31.60	[a] APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX] [a] Olmekar HCT 40/10/12.5 [RF]	[a] Olamlo HCT 40/10/12.5 [AL]
			[B]8.52	*40.47	31.60	[a] Sevikar HCT 40/10/12.5 [AF]	

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13512E NP	2	5	..	*34.25	31.60	[a] APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX] [a] Olmekar HCT 40/5/25 [RF]	[a] Olamlo HCT 40/5/25 [AL]
			[B]5.34	*39.59	31.60	[a] Sevikar HCT 40/5/25 [AF]	

▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14002Y NP	2	5	..	*35.01	31.60	[a] APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX] [a] Olmekar HCT 40/10/25 [RF]	[a] Olamlo HCT 40/10/25 [AL]
			[B]5.34	*40.35	31.60	[a] Sevikar HCT 40/10/25 [AF]	

▪ SACUBITRIL + VALSARTAN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Continuing therapy by a nurse practitioner may include dose titrations/changes, but only after therapy was initiated by a medical practitioner.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11680

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment**,** which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11123K NP	1	5	..	192.57	31.60	Entresto [NV]

sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11131W NP	1	5	..	192.57	31.60	Entresto [NV]

sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11122J NP	1	5	..	192.57	31.60	Entresto [NV]

▪ SACUBITRIL + VALSARTAN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Continuing therapy by a nurse practitioner may include dose titrations/changes, but only after therapy was initiated by a medical practitioner.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14254

Chronic heart failure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment**,** which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13570F NP	2	5	..	*376.67	31.60	Entresto [NV]

sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13511D NP	2	5	..	*376.67	31.60	Entresto [NV]

sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13445P NP	2	5	..	*376.67	31.60	Entresto [NV]

▪ LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS, PLAIN

HMG CoA reductase inhibitors

▪ ATORVASTATIN

atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8213G NP	1	5	..	16.17	17.62	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin SZ [HX]	[a] Blooms the Chemist Atorvastatin [IB]
						[a] BTC Atorvastatin [BG]	[a] Lipitor [AS]
						[a] Lorstat 10 [AF]	[a] NOUMED ATORVASTATIN [VO]
						[a] Pharmacor Atorvastatin [CR]	[a] Trovas [RA]

atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8214H NP	1	5	..	16.27	17.72	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin SZ [HX]	[a] Blooms the Chemist Atorvastatin [IB]
						[a] BTC Atorvastatin [BG]	[a] Lipitor [AS]

						[a] Lorstat 20 [AF]	[a] NOUMED ATORVASTATIN [VO]
						[a] Pharmacor Atorvastatin [CR]	[a] Trovas [RA]

atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8215J							
NP	1	5	..	17.17	18.62	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin SZ [HX]	[a] Blooms the Chemist Atorvastatin [IB]
						[a] BTC Atorvastatin [BG]	[a] Lipitor [AS]
						[a] Lorstat 40 [AF]	[a] NOUMED ATORVASTATIN [VO]
						[a] Pharmacor Atorvastatin [CR]	[a] Trovas [RA]

atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8521L							
NP	1	5	..	17.76	19.21	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin GH [GQ]	[a] Atorvastatin SZ [HX]
						[a] Blooms the Chemist Atorvastatin [IB]	[a] BTC Atorvastatin [BG]
						[a] Lipitor [AS]	[a] Lorstat 80 [AF]
						[a] NOUMED ATORVASTATIN [VO]	[a] Pharmacor Atorvastatin [CR]
						[a] Trovas [RA]	

▪ ATORVASTATIN

Restricted benefit

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

atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13495G							
NP	2	5	..	*18.89	20.34	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin SZ [HX]	[a] Blooms the Chemist Atorvastatin [IB]
						[a] BTC Atorvastatin [BG]	[a] Lipitor [AS]
						[a] Lorstat 10 [AF]	[a] NOUMED ATORVASTATIN [VO]
						[a] Pharmacor Atorvastatin [CR]	[a] Trovas [RA]

atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13529C							
NP	2	5	..	*19.09	20.54	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin SZ [HX]	[a] Blooms the Chemist Atorvastatin [IB]
						[a] BTC Atorvastatin [BG]	[a] Lipitor [AS]
						[a] Lorstat 20 [AF]	[a] NOUMED ATORVASTATIN [VO]
						[a] Pharmacor Atorvastatin [CR]	[a] Trovas [RA]

atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13468W							
NP	2	5	..	*20.89	22.34	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin SZ [HX]	[a] Blooms the Chemist Atorvastatin [IB]
						[a] BTC Atorvastatin [BG]	[a] Lipitor [AS]
						[a] Lorstat 40 [AF]	[a] NOUMED ATORVASTATIN [VO]
						[a] Pharmacor Atorvastatin [CR]	[a] Trovas [RA]

atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13374X							
NP	2	5	..	*22.07	23.52	[a] APO-Atorvastatin [TX]	[a] Atorvachol [RF]
						[a] Atorvastatin GH [GQ]	[a] Atorvastatin SZ [HX]
						[a] Blooms the Chemist Atorvastatin [IB]	[a] BTC Atorvastatin [BG]
						[a] Lipitor [AS]	[a] Lorstat 80 [AF]
						[a] NOUMED ATORVASTATIN [VO]	[a] Pharmacor Atorvastatin [CR]
						[a] Trovas [RA]	

▪ FLUVASTATIN

fluvastatin 80 mg modified release tablet, 28

2863Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.09	31.60	Lescol XL [NV]

NP

▪ FLUVASTATIN

Restricted benefit

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

fluvastatin 80 mg modified release tablet, 28

13558N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*60.73	31.60	Lescol XL [NV]

NP

▪ PRAVASTATIN

pravastatin sodium 10 mg tablet, 30

2833D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] APX-Pravastatin [TY] [a] Pravastatin Sandoz [SZ]	[a] Lipostat 10 [RF]
		[B]2.93	19.10	17.62	[a] Cholstat 10 [AF]	
		[B]4.95	21.12	17.62	[a] Pravachol [RW]	

NP

pravastatin sodium 20 mg tablet, 30

2834E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.44	17.89	[a] APX-Pravastatin [TY] [a] Lipostat 20 [RF]	[a] Cholstat 20 [AF] [a] Pravastatin Sandoz [SZ]
		[B]4.98	21.42	17.89	[a] Pravachol [RW]	

NP

pravastatin sodium 40 mg tablet, 30

8197K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.26	18.71	[a] APX-Pravastatin [TY] [a] Lipostat 40 [RF]	[a] Cholstat 40 [AF] [a] Pravastatin Sandoz [SZ]
		[B]4.98	22.24	18.71	[a] Pravachol [RW]	

NP

pravastatin sodium 80 mg tablet, 30

8829Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.30	20.75	[a] APX-Pravastatin [TY]	[a] Lipostat 80 [RF]
		[B]5.15	24.45	20.75	[a] Pravachol [RW]	

NP

▪ PRAVASTATIN

Restricted benefit

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

pravastatin sodium 10 mg tablet, 30

13496H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*18.89	20.34	[a] APX-Pravastatin [TY] [a] Pravastatin Sandoz [SZ]	[a] Lipostat 10 [RF]
		[B]5.86	*24.75	20.34	[a] Cholstat 10 [AF]	
		[B]9.90	*28.79	20.34	[a] Pravachol [RW]	

NP

pravastatin sodium 20 mg tablet, 30

13497J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*19.43	20.88	[a] APX-Pravastatin [TY] [a] Lipostat 20 [RF]	[a] Cholstat 20 [AF] [a] Pravastatin Sandoz [SZ]
		[B]9.96	*29.39	20.88	[a] Pravachol [RW]	

NP

pravastatin sodium 40 mg tablet, 30

13432Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.07	22.52	[a] APX-Pravastatin [TY] [a] Lipostat 40 [RF]	[a] Cholstat 40 [AF] [a] Pravastatin Sandoz [SZ]
		[B]9.96	*31.03	22.52	[a] Pravachol [RW]	

NP

pravastatin sodium 80 mg tablet, 30

13527Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*25.15	26.60	[a] APX-Pravastatin [TY]	[a] Lipostat 80 [RF]
		[B]10.30	*35.45	26.60	[a] Pravachol [RW]	

NP

▪ ROSUVASTATIN

rosuvastatin 10 mg tablet, 30

2628H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.22	18.67	[a] APO-ROSUVASTATIN [TX]	[a] APX-Rosuvastatin [TY]
					[a] Blooms Rosuvastatin [BG]	[a] Blooms the Chemist Rosuvastatin [IB]
					[a] Cavstat [AF]	[a] Crosuva 10 [RW]
					[a] Pharmacor Rosuvastatin 10 [CR]	[a] Rosuvastatin APOTEX [GX]
					[a] Rosuvastatin Lupin [GQ]	[a] Rosuvastatin RBX [RA]
					[a] Rosuvastatin Sandoz [SZ]	
		[B]4.94	22.16	18.67	[a] Crestor [FK]	

rosuvastatin 20 mg tablet, 30

2574L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.28	18.73	[a] APO-ROSUVASTATIN [TX]	[a] APX-Rosuvastatin [TY]
					[a] Blooms Rosuvastatin [BG]	[a] Blooms the Chemist Rosuvastatin [IB]
					[a] Cavstat [AF]	[a] Crosuva 20 [RW]
					[a] Pharmacor Rosuvastatin 20 [CR]	[a] Rosuvastatin APOTEX [GX]
					[a] Rosuvastatin Lupin [GQ]	[a] Rosuvastatin RBX [RA]
					[a] Rosuvastatin Sandoz [SZ]	
		[B]4.94	22.22	18.73	[a] Crestor [FK]	

rosuvastatin 40 mg tablet, 30

2594M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.90	20.35	[a] APO-ROSUVASTATIN [TX]	[a] APX-Rosuvastatin [TY]
					[a] Blooms Rosuvastatin [BG]	[a] Blooms the Chemist Rosuvastatin [IB]
					[a] Cavstat [AF]	[a] Crosuva 40 [RW]
					[a] Pharmacor Rosuvastatin 40 [CR]	[a] Rosuvastatin APOTEX [GX]
					[a] Rosuvastatin Lupin [GQ]	[a] Rosuvastatin RBX [RA]
					[a] Rosuvastatin Sandoz [SZ]	
		[B]4.94	23.84	20.35	[a] Crestor [FK]	

rosuvastatin 5 mg tablet, 30

2606E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.17	17.62	[a] APX-Rosuvastatin [TY]	[a] Blooms Rosuvastatin [BG]
					[a] Blooms the Chemist Rosuvastatin [IB]	[a] Cavstat [AF]
					[a] Crosuva 5 [RW]	[a] Pharmacor Rosuvastatin 5 [CR]
					[a] Rosuvastatin APOTEX [GX]	[a] Rosuvastatin Lupin [GQ]
					[a] Rosuvastatin RBX [RA]	[a] Rosuvastatin Sandoz [SZ]
		[B]4.93	21.10	17.62	[a] Crestor [FK]	

▪ ROSUVASTATIN

Restricted benefit

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

rosuvastatin 10 mg tablet, 30

13586C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] APO-ROSUVASTATIN [TX]	[a] APX-Rosuvastatin [TY]
					[a] Blooms Rosuvastatin [BG]	[a] Blooms the Chemist Rosuvastatin [IB]
					[a] Cavstat [AF]	[a] Crosuva 10 [RW]
					[a] Pharmacor Rosuvastatin 10 [CR]	[a] Rosuvastatin APOTEX [GX]
					[a] Rosuvastatin Lupin [GQ]	[a] Rosuvastatin RBX [RA]
					[a] Rosuvastatin Sandoz [SZ]	
		[B]9.88	*30.87	22.44	[a] Crestor [FK]	

rosuvastatin 20 mg tablet, 30

13588E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.11	22.56	[a] APO-ROSUVASTATIN [TX]	[a] APX-Rosuvastatin [TY]
					[a] Blooms Rosuvastatin [BG]	[a] Blooms the Chemist Rosuvastatin [IB]
					[a] Cavstat [AF]	[a] Crosuva 20 [RW]

						[a] Pharmacor Rosuvastatin 20 [CR]	[a] Rosuvastatin APOTEX [GX]
						[a] Rosuvastatin Lupin [GQ]	[a] Rosuvastatin RBX [RA]
						[a] Rosuvastatin Sandoz [SZ]	
			[B]9.88	*30.99	22.56	[a] Crestor [FK]	

rosuvastatin 40 mg tablet, 30

13589F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.35	25.80	[a] APO-ROSUVASTATIN [TX]	[a] APX-Rosuvastatin [TY]
						[a] Blooms Rosuvastatin [BG]	[a] Blooms the Chemist Rosuvastatin [IB]
						[a] Cavstat [AF]	[a] Crosuva 40 [RW]
						[a] Pharmacor Rosuvastatin 40 [CR]	[a] Rosuvastatin APOTEX [GX]
						[a] Rosuvastatin Lupin [GQ]	[a] Rosuvastatin RBX [RA]
						[a] Rosuvastatin Sandoz [SZ]	
			[B]9.88	*34.23	25.80	[a] Crestor [FK]	

rosuvastatin 5 mg tablet, 30

13406N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] APX-Rosuvastatin [TY]	[a] Blooms Rosuvastatin [BG]
						[a] Blooms the Chemist Rosuvastatin [IB]	[a] Cavstat [AF]
						[a] Crosuva 5 [RW]	[a] Pharmacor Rosuvastatin 5 [CR]
						[a] Rosuvastatin APOTEX [GX]	[a] Rosuvastatin Lupin [GQ]
						[a] Rosuvastatin RBX [RA]	[a] Rosuvastatin Sandoz [SZ]
			[B]9.86	*28.75	20.34	[a] Crestor [FK]	

▪ SIMVASTATIN

simvastatin 10 mg tablet, 30

2011W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	[a] APO-Simvastatin [TX]	[a] NOUMED SIMVASTATIN [VO]
						[a] Simvar 10 [RW]	[a] Simvastatin Sandoz [SZ]
						[a] Zimstat [AF]	

simvastatin 20 mg tablet, 30

2012X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	[a] APO-Simvastatin [TX]	[a] NOUMED SIMVASTATIN [VO]
						[a] Simvar 20 [RW]	[a] Simvastatin Sandoz [SZ]
						[a] Zimstat [AF]	
			[B]9.28	25.45	17.62	[a] Lipex 20 [AL]	[a] Zocor [MQ]

simvastatin 40 mg tablet, 30

8173E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.34	17.79	[a] APO-Simvastatin [TX]	[a] NOUMED SIMVASTATIN [VO]
						[a] Simvar 40 [RW]	[a] Simvastatin Sandoz [SZ]
						[a] Zimstat [AF]	
			[B]9.24	25.58	17.79	[a] Lipex 40 [AL]	[a] Zocor [MQ]

simvastatin 5 mg tablet, 30

2013Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	[a] Simvastatin Sandoz [SZ]	[a] Zimstat [AF]

simvastatin 80 mg tablet, 30

8313M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	[a] APO-Simvastatin [TX]	[a] Simvar 80 [RW]
						[a] Simvastatin Sandoz [SZ]	[a] Zimstat [AF]

▪ SIMVASTATIN

Restricted benefit

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

simvastatin 10 mg tablet, 30

13528B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] APO-Simvastatin [TX]	[a] NOUMED SIMVASTATIN [VO]
						[a] Simvar 10 [RW]	[a] Simvastatin Sandoz [SZ]
						[a] Zimstat [AF]	

simvastatin 20 mg tablet, 30

13373W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] APO-Simvastatin [TX] [a] Simvar 20 [RW] [a] Zimstat [AF]	[a] NOUMED SIMVASTATIN [VO] [a] Simvastatin Sandoz [SZ]
			[B]18.56	*37.45	20.34	[a] Lipex 20 [AL]	[a] Zocor [MQ]

simvastatin 40 mg tablet, 30

13471B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.23	20.68	[a] APO-Simvastatin [TX] [a] Simvar 40 [RW] [a] Zimstat [AF]	[a] NOUMED SIMVASTATIN [VO] [a] Simvastatin Sandoz [SZ]
			[B]18.48	*37.71	20.68	[a] Lipex 40 [AL]	[a] Zocor [MQ]

simvastatin 5 mg tablet, 30

13559P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Simvastatin Sandoz [SZ]	[a] Zimstat [AF]

simvastatin 80 mg tablet, 30

13498K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	[a] APO-Simvastatin [TX] [a] Simvastatin Sandoz [SZ]	[a] Simvar 80 [RW] [a] Zimstat [AF]

Fibrates

▪ FENOFIBRATE

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

fenofibrate 145 mg tablet, 30

9023X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.58	24.03	[a] APO-Fenofibrate [TX] [a] BTC Fenofibrate [BG] [a] Fenofibrate Cipla [LR] [a] Fenofibrate Sandoz [SZ] [a] Lipidil [GO]	[a] Blooms the Chemist Fenofibrate [IB] [a] Fenocol [XT] [a] FENOFIBRATE RBX [RA] [a] Fenofibrate Viatris [AL]

fenofibrate 48 mg tablet, 60

9022W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.55	21.00	[a] APO-Fenofibrate [TX] [a] FENOFIBRATE RBX [RA] [a] Lipidil [GO]	[a] Fenofibrate Cipla [LR] [a] Fenofibrate Viatris [AL]

▪ FENOFIBRATE

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

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

fenofibrate 145 mg tablet, 30

13587D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*31.71	31.60	[a] APO-Fenofibrate [TX] [a] BTC Fenofibrate [BG] [a] Fenofibrate Cipla [LR] [a] Fenofibrate Sandoz [SZ] [a] Lipidil [GO]	[a] Blooms the Chemist Fenofibrate [IB] [a] Fenocol [XT] [a] FENOFIBRATE RBX [RA] [a] Fenofibrate Viatris [AL]

fenofibrate 48 mg tablet, 60

13469X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.65	27.10	[a] APO-Fenofibrate [TX] [a] FENOFIBRATE RBX [RA] [a] Lipidil [GO]	[a] Fenofibrate Cipla [LR] [a] Fenofibrate Viatris [AL]

▪ GEMFIBROZIL

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high

cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

gemfibrozil 600 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1453L NP	1	5	..	23.36	24.81	[a] Ausgem [RW]	[a] Lipigem [AF]

▪ GEMFIBROZIL

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

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

gemfibrozil 600 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13618R NP	2	5	..	*33.27	31.60	[a] Ausgem [RW]	[a] Lipigem [AF]

Bile acid sequestrants

▪ COLESTYRAMINE

colestyramine 4 g powder for oral liquid, 60 pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14132T NP	2	5	..	*253.57	31.60	Cholestyramine (Ascend, USA) [CR]

colestyramine 4 g powder for oral liquid, 50 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2967E NP	2	5	..	*82.89	31.60	Questran Lite [GO]

colestyramine 4 g powder for oral liquid, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13351Q NP	3.33	5	..	*222.91	31.60	Cholestyramine-Odan [DZ]

▪ COLESTYRAMINE

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

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

Restricted benefit

Primary hypercholesterolaemia

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

colestyramine 4 g powder for oral liquid, 60 pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14145L	2	11	..	*253.57	31.60	Cholestyramine (Ascend, USA) [CR]

colestyramine 4 g powder for oral liquid, 50 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9249T	2	11	..	*82.89	31.60	Questran Lite [GO]

colestyramine 4 g powder for oral liquid, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13347L	3.33	11	..	*222.91	31.60	Cholestyramine-Odan [DZ]

Other lipid modifying agents

▪ ALIROCUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15201

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

Authority required (STREAMLINED)

15177

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

alirocumab 150 mg/mL injection, 2 x 1 mL pen devices

12608N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	499.63	31.60	Praluent [SW]

alirocumab 75 mg/mL injection, 2 x 1 mL pen devices

12607M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	499.63	31.60	Praluent [SW]

▪ ALIROCUMAB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

Authority required

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre prior to commencing treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years or more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

alirocumab 150 mg/mL injection, 2 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12604J	1	5	..	499.63	31.60	Praluent [SW]

alirocumab 75 mg/mL injection, 2 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12613W	1	5	..	499.63	31.60	Praluent [SW]

▪ EVOLOCUMAB

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10388

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

evolocumab 140 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11977J	3	5	..	*504.66	31.60	Repatha [AN]

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11972D	1	5	..	366.68	31.60	Repatha [AN]

▪ EVOLOCUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15432

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

evolocumab 140 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10958R	3	5	..	*504.66	31.60	Repatha [AN]

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11193D	1	5	..	366.68	31.60	Repatha [AN]

▪ EVOLOCUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15410

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

Authority required (STREAMLINED)

15395

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years of more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

evolocumab 140 mg/mL injection, 1 mL pen device

11484K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*339.25	31.60	Repatha [AN]

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

11485L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	366.68	31.60	Repatha [AN]

▪ EVOLOCUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15201

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

Authority required (STREAMLINED)

15177

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

evolocumab 140 mg/mL injection, 1 mL pen device

11985T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*339.25	31.60	Repatha [AN]

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

11986W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	366.68	31.60	Repatha [AN]

▪ EZETIMIBE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7996

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7966

Hypercholesterolaemia

Clinical criteria:

- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

Authority required (STREAMLINED)

7990

Hypercholesterolaemia

Clinical criteria:

- Patient must have homozygous sitosterolaemia.

ezetimibe 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8757X NP	1	5	..	19.10	20.55	[a] APO-Ezetimibe [TX]	[a] Blooms The Chemist Ezetimibe [IB]
						[a] BTC Ezetimibe [BG]	[a] EZEMICHOL [RW]
						[a] Ezetimibe GH [GQ]	[a] Ezetimibe Sandoz [SZ]
						[a] Pharmacor Ezetimibe 10 [CR]	[a] Zient 10mg [AF]
			[B]2.16	21.26	20.55	[a] Ezetrol [AL]	

▪ EZETIMIBE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14249

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

14283

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR

- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

Authority required (STREAMLINED)

14310

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have homozygous sitosterolaemia.

ezetimibe 10 mg tablet, 30

13440J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*24.75	26.20	[a] APO-Ezetimibe [TX]	[a] Blooms The Chemist Ezetimibe [IB]
					[a] BTC Ezetimibe [BG]	[a] EZEMICHOL [RW]
					[a] Ezetimibe GH [GQ]	[a] Ezetimibe Sandoz [SZ]
					[a] Pharmacor Ezetimibe 10 [CR]	[a] Zient 10mg [AF]
		[B]4.32	*29.07	26.20	[a] Ezetrol [AL]	

▪ INCLISIRAN

Note Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.

Note Authority applications for increased repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 888 333.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15065

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Authority required (STREAMLINED)

15110

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14087K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1849.47	31.60	Leqvio [NV]

▪ INCLISIRAN

Note Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

Authority required

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years or more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14101E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1849.47	31.60	Leqvio [NV]

▪ INCLISIRAN

Note Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.

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

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Familial heterozygous hypercholesterolaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR
- Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR

- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

Authority required

Non-familial hypercholesterolaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR

- Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years or more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14152W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1849.47	31.60	Leqvio [NV]

LIPID MODIFYING AGENTS, COMBINATIONS

Combinations of various lipid modifying agents

▪ EZETIMIBE (&) ROSUVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7957

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60

10208G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP ‡1	5	..	22.10	23.55	[a] Ezalo Composite Pack 10mg+10mg [AF]	[a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]
		[B]2.97	25.07	23.55	[a] Rosuzet Composite Pack [AL]	

ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60

10201X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP ‡1	5	..	21.93	23.38	[a] Ezalo Composite Pack 10mg+20mg [AF]	[a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]
		[B]2.98	24.91	23.38	[a] Rosuzet Composite Pack [AL]	

ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60

10207F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP ‡1	5	..	23.07	24.52	[a] Ezalo Composite Pack 10mg+40mg [AF]	[a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]
		[B]3.09	26.16	24.52	[a] Rosuzet Composite Pack [AL]	

▪ EZETIMIBE (&) ROSUVASTATIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7958

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60

10204C

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	20.72	22.17	[a] Ezalo Composite Pack 10mg+5mg [AF]
		[B]2.87	23.59	22.17	[a] Rosuzet Composite Pack [AL]

▪ EZETIMIBE (&) ROSUVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14284

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR

- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60

13569E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡2	5	..	*30.75	31.60	[a] Ezalo Composite Pack 10mg+10mg [AF]	[a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]
		[B]5.94	*36.69	31.60	[a] Rosuzet Composite Pack [AL]	

ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60

13480L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡2	5	..	*30.41	31.60	[a] Ezalo Composite Pack 10mg+20mg [AF]	[a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]
		[B]5.96	*36.37	31.60	[a] Rosuzet Composite Pack [AL]	

ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60

13537L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡2	5	..	*32.69	31.60	[a] Ezalo Composite Pack 10mg+40mg [AF]	[a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]
		[B]6.18	*38.87	31.60	[a] Rosuzet Composite Pack [AL]	

▪ EZETIMIBE (&) ROSUVASTATIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

14350

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60

13629H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*27.99	29.44	[a] Ezalo Composite Pack 10mg+5mg [AF]
		[B]5.74	*33.73	29.44	[a] Rosuzet Composite Pack [AL]

▪ EZETIMIBE + ATORVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7957

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + atorvastatin 40 mg tablet, 30

10377E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	22.42	23.87	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/40 [GQ]
		[B]2.22	24.64	23.87	[a] Atozet [AF]	

ezetimibe 10 mg + atorvastatin 80 mg tablet, 30

10376D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.41	24.86	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/80 [GQ]
		[B]2.21	25.62	24.86	[a] Atozet [AF]	

ezetimibe 10 mg + atorvastatin 20 mg tablet, 30

10393B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	21.51	22.96	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/20 [GQ]

	[B]2.16	23.67	22.96	[a] Atozet [AF]	

▪ EZETIMIBE + ATORVASTATIN

Note Continuing Therapy Only:

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Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7958

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg + atorvastatin 10 mg tablet, 30

10392Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.95	22.40	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/10 [GQ]
		[B]2.15	23.10	22.40	[a] Atozet [AF]	

▪ EZETIMIBE + ATORVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14284

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR

- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13416D NP	2	5	..	*31.39	31.60	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/40 [GQ]
			[B]4.44	*35.83	31.60	[a] Atozet [AF]	

ezetimibe 10 mg + atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13538M NP	2	5	..	*33.37	31.60	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/80 [GQ]
			[B]4.42	*37.79	31.60	[a] Atozet [AF]	

▪ EZETIMIBE + ATORVASTATIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

14269

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg + atorvastatin 10 mg tablet, 30

13539N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*28.45	29.90	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/10 [GQ]
		[B]4.30	*32.75	29.90	[a] Atozet [AF]	

▪ EZETIMIBE + ATORVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14348

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + atorvastatin 20 mg tablet, 30

13622Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*29.57	31.02	[a] Ezetast [XT]	[a] Ezetimibe/Atorvastatin GH 10/20 [GQ]
		[B]4.32	*33.89	31.02	[a] Atozet [AF]	

▪ EZETIMIBE + SIMVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7957

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**

- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + simvastatin 80 mg tablet, 30

8882L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.64	25.09	[a] APO-Ezetimibe/Simvastatin 10/80 [TX]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ]
					[a] EZETORIN [RW]	[a] EzSimva GH 10/80 [GQ]
					[a] Pharmacor Ezetimibe Simvastatin 10/80 [CR]	[a] Vytorin [AL]
					[a] Zeklen 10/80 mg [AF]	[a] Zimybe 10/80 [MQ]

ezetimibe 10 mg + simvastatin 40 mg tablet, 30

8881K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	22.81	24.26	[a] APO-Ezetimibe/Simvastatin 10/40 [TX]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ]
					[a] EZETORIN [RW]	[a] EzSimva GH 10/40 [GQ]
					[a] Pharmacor Ezetimibe Simvastatin 10/40 [CR]	[a] Vytorin [AL]
					[a] Zeklen 10/40 mg [AF]	[a] Zimybe 10/40 [MQ]

▪ EZETIMIBE + SIMVASTATIN

Note Continuing Therapy Only:

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Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7958

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR

- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg + simvastatin 10 mg tablet, 30

9483D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	21.80	23.25	[a] APO-Ezetimibe/Simvastatin 10/10 [TX]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ]
					[a] EZETORIN [RW]	[a] EzSimva GH 10/10 [GQ]
					[a] Pharmacor Ezetimibe Simvastatin 10/10 [CR]	[a] Vytorin [AL]
					[a] Zeklen 10/10 mg [AF]	[a] Zimybe 10/10 [MQ]

ezetimibe 10 mg + simvastatin 20 mg tablet, 30

9484E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	22.22	23.67	[a] APO-Ezetimibe/Simvastatin 10/20 [TX]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ]
					[a] EZETORIN [RW]	[a] EzSimva GH 10/20 [GQ]
					[a] Pharmacor Ezetimibe Simvastatin 10/20 [CR]	[a] Vytorin [AL]
					[a] Zeklen 10/20 mg [AF]	[a] Zimybe 10/20 [MQ]

▪ EZETIMIBE + SIMVASTATIN

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Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

14269

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg + simvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13385L NP	2	5	..	*30.15	31.60	[a] APO-Ezetimibe/Simvastatin 10/10 [TX] [a] EZETORIN [RW] [a] Pharmacor Ezetimibe Simvastatin 10/10 [CR] [a] Zeklen 10/10 mg [AF]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] [a] EzSimva GH 10/10 [GQ] [a] Vytorin [AL] [a] Zimybe 10/10 [MQ]

ezetimibe 10 mg + simvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13442L NP	2	5	..	*30.99	31.60	[a] APO-Ezetimibe/Simvastatin 10/20 [TX] [a] EZETORIN [RW] [a] Pharmacor Ezetimibe Simvastatin 10/20 [CR] [a] Zeklen 10/20 mg [AF]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] [a] EzSimva GH 10/20 [GQ] [a] Vytorin [AL] [a] Zimybe 10/20 [MQ]

▪ EZETIMIBE + SIMVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14284

Hypercholesterolaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + simvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13595M NP	2	5	..	*33.83	31.60	[a] APO-Ezetimibe/Simvastatin 10/80 [TX] [a] EZETORIN [RW] [a] Pharmacor Ezetimibe Simvastatin 10/80 [CR] [a] Zeklen 10/80 mg [AF]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] [a] EzSimva GH 10/80 [GQ] [a] Vytorin [AL] [a] Zimybe 10/80 [MQ]

ezetimibe 10 mg + simvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13535J NP	2	5	..	*32.17	31.60	[a] APO-Ezetimibe/Simvastatin 10/40 [TX] [a] EZETORIN [RW] [a] Pharmacor Ezetimibe Simvastatin 10/40 [CR] [a] Zeklen 10/40 mg [AF]	[a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] [a] EzSimva GH 10/40 [GQ] [a] Vytorin [AL] [a] Zimybe 10/40 [MQ]

Lipid modifying agents in combination with other drugs

▪ AMLODIPINE + ATORVASTATIN

amlodipine 10 mg + atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9053L NP	1	5	..	17.10	18.55	[a] Cadivast 10/10 [AF]
			[B]5.00	22.10	18.55	[a] Caduet 10/10 [AS]

amlodipine 10 mg + atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9054M NP	1	5	..	17.30	18.75	[a] Cadivast 10/20 [AF]
			[B]5.00	22.30	18.75	[a] Caduet 10/20 [AS]

amlodipine 10 mg + atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9055N NP	1	5	..	18.21	19.66	[a] Cadivast 10/40 [AF]
			[B]5.00	23.21	19.66	[a] Caduet 10/40 [AS]

amlodipine 10 mg + atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9056P NP	1	5	..	19.58	21.03	[a] Cadivast 10/80 [AF]
			[B]5.00	24.58	21.03	[a] Caduet 10/80 [AS]

amlodipine 5 mg + atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9049G NP	1	5	..	16.42	17.87	Cadivast 5/10 [AF]

amlodipine 5 mg + atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9050H NP	1	5	..	17.15	18.60	Cadivast 5/20 [AF]

amlodipine 5 mg + atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9051J NP	1	5	..	17.52	18.97	[a] Cadivast 5/40 [AF]
			[B]5.00	22.52	18.97	[a] Caduet 5/40 [AS]

amlodipine 5 mg + atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9052K NP	1	5	..	18.89	20.34	[a] Cadivast 5/80 [AF]
			[B]5.00	23.89	20.34	[a] Caduet 5/80 [AS]

▪ AMLODIPINE + ATORVASTATIN

Restricted benefit

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

amlodipine 10 mg + atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13479K NP	2	5	..	*20.75	22.20	[a] Cadivast 10/10 [AF]
			[B]10.00	*30.75	22.20	[a] Caduet 10/10 [AS]

amlodipine 10 mg + atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13384K NP	2	5	..	*21.15	22.60	[a] Cadivast 10/20 [AF]
			[B]10.00	*31.15	22.60	[a] Caduet 10/20 [AS]

amlodipine 10 mg + atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13536K NP	2	5	..	*22.97	24.42	[a] Cadivast 10/40 [AF]
			[B]10.00	*32.97	24.42	[a] Caduet 10/40 [AS]

amlodipine 10 mg + atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*25.71	27.16	[a] Cadivast 10/80 [AF]

13963X			[B]10.00	*35.71	27.16	[a] Caduet 10/80 [AS]

NP

amlodipine 5 mg + atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13596N	2	5	..	*19.39	20.84	Cadivast 5/10 [AF]

NP

amlodipine 5 mg + atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13567C	2	5	..	*20.85	22.30	Cadivast 5/20 [AF]

NP

amlodipine 5 mg + atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13415C	2	5	..	*21.59	23.04	[a] Cadivast 5/40 [AF]
			[B]10.00	*31.59	23.04	[a] Caduet 5/40 [AS]

NP

amlodipine 5 mg + atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13597P	2	5	..	*24.33	25.78	[a] Cadivast 5/80 [AF]
			[B]10.00	*34.33	25.78	[a] Caduet 5/80 [AS]

NP

▪ DERMATOLOGICALS

▪ ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Imidazole and triazole derivatives

▪ MICONAZOLE

Authority required (STREAMLINED)

6434

Fungal or yeast infection

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

miconazole 2% solution, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9031H	‡1	2	..	21.93	23.38	Daktarin Tincture [JT]

NP

miconazole nitrate 2% cream, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9027D	‡1	2	..	19.03	20.48	Daktarin [JT]

NP

miconazole nitrate 2% cream, 70 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9028E	‡1	1	..	20.24	21.69	Daktarin [JT]

NP

miconazole nitrate 2% powder, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9029F	‡1	2	..	19.53	20.98	Daktarin [JT]

NP

Other antifungals for topical use

▪ TERBINAFINE

Authority required (STREAMLINED)

6434

Fungal or yeast infection

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)

6412

Fungal or yeast infection

Clinical criteria:

- The condition must be fungal; OR
- The condition must be due to yeast.

Population criteria:

- Patient must be 18 years of age or less.

terbinafine hydrochloride 1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9160D NP	2	3	..	*40.37	31.60	Lamisil [NP]

ANTIFUNGALS FOR SYSTEMIC USE

Antifungals for systemic use

▪ GRISEOFULVIN

griseofulvin 125 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1460W NP	1	2	..	24.14	25.59	Grisovin [AS]

griseofulvin 500 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2982Y NP	1	2	..	24.77	26.22	Grisovin 500 [AS]

▪ TERBINAFINE

Authority required

Dermatophyte infection

Clinical criteria:

- Patient must have failed to respond to topical treatment.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required

Dermatophyte infection

Clinical criteria:

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

Population criteria:

- Patient must be 18 years of age or less.

terbinafine 250 mg tablet, 42

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2285G NP	1	..	..	28.82	30.27	[a] APO-Terbinafine [TX]	[a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
						[a] NOUMED TERBINAFINE [VO]	[a] Tamsil [RW]
						[a] Terbinafine-DRLA [RZ]	[a] Terbinafine Sandoz [SZ]
						[a] Tinasil [AF]	

▪ TERBINAFINE

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

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

Authority required

Onychomycosis

Clinical criteria:

- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

terbinafine 250 mg tablet, 42

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2804N NP	1	1	..	28.82	30.27	[a] APO-Terbinafine [TX]	[a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
						[a] NOUMED TERBINAFINE [VO]	[a] Tamsil [RW]
						[a] Terbinafine-DRLA [RZ]	[a] Terbinafine Sandoz [SZ]
						[a] Tinasil [AF]	

▪ ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Other antipsoriatics for topical use

▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9494Q NP	‡1	1	..	39.47	31.60	[a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	[a] Daivobet [LO]

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11091R NP	‡1	1	..	85.70	31.60	Enstilar [LO]

▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13577N NP	‡2	1	..	*65.49	31.60	[a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	[a] Daivobet [LO]

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13520N NP	‡2	1	..	*160.17	31.60	Enstilar [LO]

ANTIPSORIATICS FOR SYSTEMIC USE

Retinoids for treatment of psoriasis

▪ ACITRETIN

Caution This drug is a potent teratogen - pregnancy should be avoided during therapy and for at least three years after cessation of therapy.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5789

Severe intractable psoriasis

Authority required (STREAMLINED)

5727

Severe disorders of keratinisation

acitretin 10 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2019G	1	2	..	109.71	31.60	[a] Neotigason [TB]	[a] ZETIN [RW]

acitretin 25 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2020H	1	2	..	213.99	31.60	[a] Neotigason [TB]	[a] ZETIN [RW]

▪ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

CHEMOTHERAPEUTICS FOR TOPICAL USE

Sulfonamides

▪ SILVER SULFADIAZINE

Restricted benefit

Infection

Treatment Phase: Prevention and treatment

Clinical criteria:

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

Restricted benefit

Stasis ulcers

silver sulfadiazine 1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9479X NP	‡1	..	..	22.93	24.38	Flamazine [SN]

▪ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, weak (group I)

▪ HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2881P NP	‡1	1	..	16.37	17.82	[a] Cortic-DS 1% [LN]
			[B]2.19	18.56	17.82	[a] Sigmacort [AS]

hydrocortisone acetate 1% ointment, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2882Q NP	‡1	1	..	16.37	17.82	[a] Cortic-DS 1% [LN]
			[B]2.19	18.56	17.82	[a] Sigmacort [AS]

▪ HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5113D DP	‡1	..	..	16.37	17.82	[a] Cortic-DS 1% [LN]
			[B]2.19	18.56	17.82	[a] Sigmacort [AS]

hydrocortisone acetate 1% ointment, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5114E DP	‡1	..	..	16.37	17.82	[a] Cortic-DS 1% [LN]
			[B]2.19	18.56	17.82	[a] Sigmacort [AS]

Corticosteroids, moderately potent (group II)

▪ TRIAMCINOLONE

Restricted benefit

Corticosteroid-responsive dermatoses

triamcinolone acetonide 0.02% cream, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2117K NP	2	..	..	*20.99	22.44	[a] Tricortone [LN]
			[B]3.28	*24.27	22.44	[a] Aristocort 0.02% [AS]

triamcinolone acetonide 0.02% ointment, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2118L NP	2	..	..	*20.99	22.44	[a] Tricortone [LN]
			[B]3.28	*24.27	22.44	[a] Aristocort 0.02% [AS]

Corticosteroids, potent (group III)

▪ BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

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Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as dipropionate) 0.05% cream, 15 g

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	17.38	18.83	[a] Eleuphrat [AL]

1115Q			[B]2.45	19.83	18.83	[a] Diprosone [AF]

NP

betamethasone (as dipropionate) 0.05% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1119X	1	1	..	17.38	18.83	[a] Eleuphrat [AL]
			[B]2.45	19.83	18.83	[a] Diprosone [AF]

NP

▪ BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6232

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10824Q	2	5	..	*21.31	22.76	[a] Eleuphrat [AL]
			[B]4.90	*26.21	22.76	[a] Diprosone [AF]

NP

betamethasone (as dipropionate) 0.05% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10795E	2	5	..	*21.31	22.76	[a] Eleuphrat [AL]
			[B]4.90	*26.21	22.76	[a] Diprosone [AF]

NP

▪ BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6246

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10800K	4	5	..	*29.15	30.60	[a] Eleuphrat [AL]
			[B]9.80	*38.95	30.60	[a] Diprosone [AF]

NP

betamethasone (as dipropionate) 0.05% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10820L	4	5	..	*29.15	30.60	[a] Eleuphrat [AL]
			[B]9.80	*38.95	30.60	[a] Diprosone [AF]

NP

▪ BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10813D	6	5	..	*36.99	31.60	[a] Eleuphrat [AL]
			[B]14.70	*51.69	31.60	[a] Diprosone [AF]

NP

betamethasone (as dipropionate) 0.05% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10821M	6	5	..	*36.99	31.60	[a] Eleuphrat [AL]
			[B]14.70	*51.69	31.60	[a] Diprosone [AF]

NP

▪ BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10801L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*44.83	31.60	[a] Eleuphrat [AL]
		[B]19.60	*64.43	31.60	[a] Diprosone [AF]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10816G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*44.83	31.60	[a] Eleuphrat [AL]
		[B]19.60	*64.43	31.60	[a] Diprosone [AF]

▪ BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6231

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10802M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	5	..	*52.67	31.60	[a] Eleuphrat [AL]
		[B]24.50	*77.17	31.60	[a] Diprosone [AF]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10823P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	5	..	*52.67	31.60	[a] Eleuphrat [AL]
		[B]24.50	*77.17	31.60	[a] Diprosone [AF]

▪ BETAMETHASONE VALERATE

Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.02% cream, 100 g

2812B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*24.07	25.52	[a] Antroquoril [AL] [b] Cortival 1/5 [LN]
		[B]4.10	*28.17	25.52	[b] Betnovate 1/5 [AS]
		[B]5.00	*29.07	25.52	[a] Celestone-M [AF]

▪ BETAMETHASONE VALERATE

Note Continuing Therapy Only:

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Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.05% cream, 15 g

2813C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	16.15	17.60	[a] Cortival 1/2 [LN]
		[B]2.56	18.71	17.60	[a] Betnovate 1/2 [AS]

▪ BETAMETHASONE VALERATE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6232

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10799J

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*18.85	20.30	[a] Cortival 1/2 [LN]
		[B]5.12	*23.97	20.30	[a] Betnovate 1/2 [AS]

▪ BETAMETHASONE VALERATE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6246

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10794D

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*24.23	25.68	[a] Cortival 1/2 [LN]
		[B]10.24	*34.47	25.68	[a] Betnovate 1/2 [AS]

▪ BETAMETHASONE VALERATE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10808W

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*29.61	31.06	[a] Cortival 1/2 [LN]
		[B]15.36	*44.97	31.06	[a] Betnovate 1/2 [AS]

▪ BETAMETHASONE VALERATE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10807T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*34.99	31.60	[a] Cortival 1/2 [LN]
		[B]20.48	*55.47	31.60	[a] Betnovate 1/2 [AS]

▪ BETAMETHASONE VALERATE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6231

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10810Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	5	..	*40.37	31.60	[a] Cortival 1/2 [LN]
		[B]25.60	*65.97	31.60	[a] Betnovate 1/2 [AS]

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Corticosteroid-responsive dermatoses

methylprednisolone aceponate 0.1% cream, 15 g

8054X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	18.78	20.23	[a] Supriad Cream [XT]
		[B]3.94	22.72	20.23	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

8055Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	18.78	20.23	[a] Supriad Ointment [XT]
		[B]3.94	22.72	20.23	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

8128T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	18.78	20.23	[a] Supriad Fatty Ointment [XT]	[a] Tanilone (Fatty) [AS]
		[B]3.94	22.72	20.23	[a] Advantan (Fatty) [LO]	

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

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Restricted benefit

Eczema

methylprednisolone aceponate 0.1% lotion, 20 g

8618N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	19.43	20.88	Advantan [LO]

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6232

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

methylprednisolone aceponate 0.1% cream, 15 g

10842P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*24.11	25.56	[a] Supriad Cream [XT]
		[B]7.88	*31.99	25.56	[a] Advantan [LO]

methylprednisolone aceponate 0.1% lotion, 20 g

10856J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*25.41	26.86	Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

10846W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*24.11	25.56	[a] Supriad Ointment [XT]
		[B]7.88	*31.99	25.56	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

10848Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*24.11	25.56	[a] Supriad Fatty Ointment [XT]	[a] Tanilone (Fatty) [AS]
		[B]7.88	*31.99	25.56	[a] Advantan (Fatty) [LO]	

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6246

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

methylprednisolone aceponate 0.1% cream, 15 g

10855H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*34.75	31.60	[a] Supriad Cream [XT]
		[B]15.76	*50.51	31.60	[a] Advantan [LO]

methylprednisolone aceponate 0.1% lotion, 20 g

10838K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*31.38	31.60	Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

10836H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*34.75	31.60	[a] Supriad Ointment [XT]
		[B]15.76	*50.51	31.60	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

10840M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*34.75	31.60	[a] Supriad Fatty Ointment [XT]	[a] Tanilone (Fatty) [AS]
		[B]15.76	*50.51	31.60	[a] Advantan (Fatty) [LO]	

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6231

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

methylprednisolone aceponate 0.1% cream, 15 g

10833E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	5	..	*66.67	31.60	[a] Supriad Cream [XT]
		[B]39.40	*106.07	31.60	[a] Advantan [LO]

methylprednisolone aceponate 0.1% lotion, 20 g

10830B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	5	..	*43.32	31.60	Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

10843Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	5	..	*66.67	31.60	[a] Supriad Fatty Ointment [XT]	[a] Tanilone (Fatty) [AS]
		[B]39.40	*106.07	31.60	[a] Advantan (Fatty) [LO]	

methylprednisolone aceponate 0.1% ointment, 15 g

10845T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	5	..	*66.67	31.60	[a] Supriad Ointment [XT]
		[B]39.40	*106.07	31.60	[a] Advantan [LO]

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

methylprednisolone aceponate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10835G NP	6	5	..	*45.39	31.60	[a] Supriad Cream [XT]
			[B]23.64	*69.03	31.60	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10844R NP	6	5	..	*45.39	31.60	[a] Supriad Fatty Ointment [XT]	[a] Tanilone (Fatty) [AS]
			[B]23.64	*69.03	31.60	[a] Advantan (Fatty) [LO]	

methylprednisolone aceponate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10853F NP	6	5	..	*45.39	31.60	[a] Supriad Ointment [XT]
			[B]23.64	*69.03	31.60	[a] Advantan [LO]

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

methylprednisolone aceponate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10851D NP	8	5	..	*56.03	31.60	[a] Supriad Cream [XT]
			[B]31.52	*87.55	31.60	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10834F NP	8	5	..	*56.03	31.60	[a] Supriad Ointment [XT]
			[B]31.52	*87.55	31.60	[a] Advantan [LO]

methylprednisolone aceponate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10839L NP	8	5	..	*56.03	31.60	[a] Supriad Fatty Ointment [XT]	[a] Tanilone (Fatty) [AS]
			[B]31.52	*87.55	31.60	[a] Advantan (Fatty) [LO]	

▪ METHYLPREDNISOLONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

methylprednisolone aceponate 0.1% lotion, 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10852E NP	4	5	..	*37.35	31.60	Advantan [LO]

▪ MOMETASONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Corticosteroid-responsive dermatoses

mometasone furoate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1913Q NP	1	..	..	17.22	18.67	[a] Momasone Alcohol Free [AS]	[a] Novasone [AF]
			[B]3.53	20.75	18.67	[a] Elocon Alcohol Free [AL]	

mometasone furoate 0.1% lotion, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8043H NP	1	..	..	18.69	20.14	[a] Novasone [AF]	[a] Zatamil [EO]
			[B]3.53	22.22	20.14	[a] Elocon [AL]	

mometasone furoate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1915T NP	1	..	..	17.22	18.67	[a] Momasone [AS] [a] Zatamil [EO]	[a] Novasone [AF]
			[B]3.53	20.75	18.67	[a] Elocon [AL]	

▪ MOMETASONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6232

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

mometasone furoate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10827W NP	2	5	..	*20.99	22.44	[a] Momasone Alcohol Free [AS]	[a] Novasone [AF]
			[B]7.06	*28.05	22.44	[a] Elocon Alcohol Free [AL]	

mometasone furoate 0.1% lotion, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10819K NP	2	5	..	*23.93	25.38	[a] Novasone [AF]	[a] Zatamil [EO]
			[B]7.06	*30.99	25.38	[a] Elocon [AL]	

mometasone furoate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10812C NP	2	5	..	*20.99	22.44	[a] Momasone [AS] [a] Zatamil [EO]	[a] Novasone [AF]
			[B]7.06	*28.05	22.44	[a] Elocon [AL]	

▪ MOMETASONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6246

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

mometasone furoate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10809X NP	4	5	..	*28.51	29.96	[a] Momasone Alcohol Free [AS]	[a] Novasone [AF]
			[B]14.12	*42.63	29.96	[a] Elocon Alcohol Free [AL]	

mometasone furoate 0.1% lotion, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10826T NP	3	5	..	*29.16	30.61	[a] Novasone [AF]	[a] Zatamil [EO]
			[B]10.59	*39.75	30.61	[a] Elocon [AL]	

mometasone furoate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10814E NP	4	5	..	*28.51	29.96	[a] Momasone [AS] [a] Zatamil [EO]	[a] Novasone [AF]
			[B]14.12	*42.63	29.96	[a] Elocon [AL]	

▪ MOMETASONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

mometasone furoate 0.1% cream, 15 g

10815F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	..	*36.03	31.60	[a] Momasone Alcohol Free [AS]	[a] Novasone [AF]
		[B]21.18	*57.21	31.60	[a] Elocon Alcohol Free [AL]	

mometasone furoate 0.1% ointment, 15 g

10828X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	..	*36.03	31.60	[a] Momasone [AS] [a] Zatamil [EO]	[a] Novasone [AF]
		[B]21.18	*57.21	31.60	[a] Elocon [AL]	

▪ MOMETASONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

mometasone furoate 0.1% cream, 15 g

10818J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8	5	..	*43.55	31.60	[a] Momasone Alcohol Free [AS]	[a] Novasone [AF]
		[B]28.24	*71.79	31.60	[a] Elocon Alcohol Free [AL]	

mometasone furoate 0.1% ointment, 15 g

10793C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8	5	..	*43.55	31.60	[a] Momasone [AS] [a] Zatamil [EO]	[a] Novasone [AF]
		[B]28.24	*71.79	31.60	[a] Elocon [AL]	

▪ MOMETASONE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

6231

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

mometasone furoate 0.1% cream, 15 g

10792B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	5	..	*51.07	31.60	[a] Momasone Alcohol Free [AS]	[a] Novasone [AF]
		[B]35.30	*86.37	31.60	[a] Elocon Alcohol Free [AL]	

mometasone furoate 0.1% lotion, 30 mL

10804P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	5	..	*39.62	31.60	[a] Novasone [AF]	[a] Zatamil [EO]
		[B]17.65	*57.27	31.60	[a] Elocon [AL]	

mometasone furoate 0.1% ointment, 15 g

10791Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	5	..	*51.07	31.60	[a] Momasone [AS] [a] Zatamil [EO]	[a] Novasone [AF]
		[B]35.30	*86.37	31.60	[a] Elocon [AL]	

▪ MOMETASONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

mometasone furoate 0.1% lotion, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10805Q NP	4	5	..	*34.39	31.60	[a] Novasone [AF]	[a] Zatamil [EO]
			[B]14.12	*48.51	31.60	[a] Elocon [AL]	

Corticosteroids, very potent (group IV)

▪ CLOBETASOL

Authority required (STREAMLINED)

5461

Moderate to severe scalp psoriasis

Clinical criteria:

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

Population criteria:

- Patient must be aged 18 years or older.

clobetasol propionate 0.05% shampoo, 125 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10080M	‡1	1	..	47.50	31.60	Clobex [GA]

▪ ANTI-ACNE PREPARATIONS

ANTI-ACNE PREPARATIONS FOR TOPICAL USE

Retinoids for topical use in acne

▪ ADAPALENE + BENZOYL PEROXIDE

Restricted benefit

Severe acne vulgaris

Treatment Phase: Acute treatment

Clinical criteria:

- The treatment must in combination with an oral antibiotic.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8954G	‡1	1	..	36.15	31.60	Epiduo [GA]

▪ ADAPALENE + BENZOYL PEROXIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe acne vulgaris

Clinical criteria:

- The treatment must be maintenance therapy.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8955H NP	‡1	3	..	36.15	31.60	Epiduo [GA]

▪ ADAPALENE + BENZOYL PEROXIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe acne vulgaris

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be maintenance therapy.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

13363H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	3	..	*58.85	31.60	Epiduo [GA]

NP

ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

Retinoids for treatment of acne

▪ ISOTRETINOIN

Caution This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

- The condition must be unresponsive to other therapy.

isotretinoin 10 mg capsule, 60

2591J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	33.20	31.60	[a] APO-Isotretinoin [TX] [a] Isotretinoin GX [SZ] [a] Oratane [RF]	[a] Dermatane [ZS] [a] Isotretinoin Lupin [GQ]

isotretinoin 40 mg capsule, 30

2549E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	46.77	31.60	[a] Dermatane [ZS]	[a] Oratane [RF]

isotretinoin 30 mg capsule, 60

11921K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	63.42	31.60	Oratane [OU]

isotretinoin 5 mg capsule, 60

11716P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	25.30	26.75	Oratane [OU]

▪ ISOTRETINOIN

Caution This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

Note Pharmaceutical benefits that have form pack size isotretinoin 20 mg capsule, 60 and isotretinoin 20 mg capsule, 30 are equivalent for the purposes of substitution.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

- The condition must be unresponsive to other therapy.

isotretinoin 20 mg capsule, 60

2592K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	44.23	31.60	[a] APO-Isotretinoin [TX] [a] Isotretinoin GX [SZ] [a] Oratane [RF]	[a] Dermatane [ZS] [a] Isotretinoin Lupin [GQ] [a] Pharmacor Isotretinoin [CR]

isotretinoin 20 mg capsule, 30

11621P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*44.25	31.60	[a] Roaccutane [RO]

▪ OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Agents for dermatitis, excluding corticosteroids

▪ DUPILUMAB

Note Instructions on the use of the Eczema Area and Severity Index and copyright details can be found here: https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf

Note Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the whole body

Clinical criteria:

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Population criteria:

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

Note Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

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Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the whole body

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the face and/or hands

Clinical criteria:

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Population criteria:

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the face and/or hands

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12292Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1755.66	31.60	Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12291X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1755.66	31.60	Dupixent [SW]

▪ PIMECROLIMUS

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

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

Authority required (STREAMLINED)

5482

Atopic dermatitis

Population criteria:

- Patient must be at least 3 months of age.

Clinical criteria:

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Authority required (STREAMLINED)

5472

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

Population criteria:

- Patient must be at least 3 months of age.

Clinical criteria:

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
- The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or

(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or

(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or

(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

pimecrolimus 1% cream, 15 g

8802G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	34.03	31.60	Elidel [GO]

Other dermatologicals

▪ DAPSONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

dapsone 100 mg tablet, 100

1272Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	401.14	31.60	Link Medical Products Pty Ltd [LM]

dapsone 25 mg tablet, 100

8801F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	328.45	31.60	Link Medical Products Pty Ltd [LM]

NP

▪ IMIQUIMOD

Note The patient or carer must be able to understand and administer the imiquimod dosing regimen.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Treatment of recurrent (previously treated) lesions will not be authorised.
Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required

Superficial basal cell carcinoma

Clinical criteria:

- The condition must be previously untreated, **AND**
- The condition must be confirmed by biopsy, **AND**
- Patient must have normal immune function, **AND**
- The condition must not be suitable for treatment with surgical excision; OR
- The condition must not be suitable for treatment with cryotherapy; OR
- The condition must not be suitable for treatment with curettage with diathermy, **AND**
- Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

imiquimod 5% cream, 12 x 250 mg sachets

2546B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	88.99	31.60	[a] Aldiq [AF]	[a] APO-Imiquimod [TX]
		[B]3.30	92.29	31.60	[a] Aldara [IL]	

imiquimod 5% cream, 2 x 2 g

2637T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]8.35	97.34	31.60	[a] Aldara Pump [IL]

▪ GENITO URINARY SYSTEM AND SEX HORMONES

▪ OTHER GYNECOLOGICALS

CONTRACEPTIVES FOR TOPICAL USE

Intrauterine contraceptives

▪ LEVONORGESTREL

Restricted benefit

Contraception

levonorgestrel 19.5 mg intrauterine drug delivery system, 1 system

11909T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	171.79	31.60	Kyleena [SY]

NP

▪ LEVONORGESTREL

Restricted benefit

Contraception

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:

- The treatment must be in a patient where oral treatments are ineffective.

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:

- The treatment must be in a patient where oral treatments are contraindicated.

levonorgestrel 52 mg intrauterine drug delivery system, 1 system

8633J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	168.86	31.60	Mirena [BN]

NP

OTHER GYNECOLOGICALS

Prolactine inhibitors

▪ BROMOCRIPTINE

Restricted benefit

Prevention of the onset of lactation

Clinical criteria:

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

bromocriptine 2.5 mg tablet, 30

1444B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.09	24.54	Parlodel [SZ]

▪ BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Restricted benefit

Parkinson disease

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

1443Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*32.73	31.60	Parlodel [SZ]

▪ BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Clinical criteria:

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

Restricted benefit

Parkinson disease

Clinical criteria:

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

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

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

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

13979R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*51.99	31.60	Parlodel [SZ]

▪ CABERGOLINE

Restricted benefit

Prevention of the onset of lactation

Clinical criteria:

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

cabergoline 500 microgram tablet, 2

8115D

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.82	28.27	Dostinex [PF]

▪ CABERGOLINE

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

cabergoline 500 microgram tablet, 8

8114C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	66.92	31.60	Dostinex [PF]

▪ CABERGOLINE

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

cabergoline 500 microgram tablet, 8

13901P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*120.73	31.60	Dostinex [PF]

▪ QUINAGOLIDE

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

quinagolide 75 microgram tablet, 30

8822H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	75.35	31.60	Norprolac [FP]

▪ QUINAGOLIDE

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

quinagolide 75 microgram tablet, 30

13982X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*138.43	31.60	Norprolac [FP]

▪ SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

Progestogens and estrogens, fixed combinations

▪ LEVONORGESTREL + ETHINYLESTRADIOL

levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

1456P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	23.33	24.78	Microgynon 50 ED [BN]

levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

1394J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	17.87	19.32	[a] Eleanor 150/30 ED [XT]	[a] Evelyn 150/30 ED [GQ]
					[a] Femme-Tab ED 30/150 [AE]	[a] Lenest 30 ED [AF]
					[a] Micronelle 30 ED [TX]	
		[B]5.66	23.53	19.32	[a] Levlen ED [SY]	

levonorgestrel 100 microgram + ethinylestradiol 20 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

2416E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	19.57	21.02	Femme-Tab ED 20/100 [AE]

▪ NORETHISTERONE + ETHINYLESTRADIOL

norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

2774B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	19.44	20.89	Norimin 28 Day [FZ]

▪ NORETHISTERONE + ETHINYLESTRADIOL

Note Pharmaceutical benefits that have the form norethisterone 1 mg + ethinylestradiol 35 microgram tablet in a 4 pack of 28 tablets can be substituted for a 3 pack of 28 tablets in the case of a shortage.

norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

2775C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	19.44	20.89	Norimin-1 28 Day [FZ]

Progestogens and estrogens, sequential preparations

▪ LEVONORGESTREL + ETHINYLESTRADIOL

levonorgestrel 50 microgram + ethinylestradiol 30 microgram tablet [6] (&) levonorgestrel 75 microgram + ethinylestradiol 40 microgram tablet [5] (&) levonorgestrel 125 microgram + ethinylestradiol 30 microgram tablet [10] (&) inert substance tablet [7], 4 x 28

1392G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	21.18	22.63	Trifeme 28 [FZ]
					[a] Logynon ED [SY]
		[B]13.56	34.74	22.63	[a] Triquilar ED [BN]

Progestogens

▪ ETONOGESTREL

etonogestrel 68 mg implant, 1

8487Q NP MW

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	171.79	31.60	Implanon NXT [OQ]

▪ LEVONORGESTREL

levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]

2913H NP MW

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	21.16	22.61	Microlut 28 [BN]

▪ MEDROXYPROGESTERONE

Note Pharmaceutical benefits that have the form medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe and pharmaceutical benefits that have the form medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial are equivalent for the purposes of substitution.

medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe

14160G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	27.59	29.04	[a] Depo-Provera [PF]

medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

3118D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]7.00	34.59	29.04	[a] Depo-Provera [PF]

▪ NORETHISTERONE

norethisterone 350 microgram tablet, 4 x 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1967M NP	1	2	..	19.44	20.89	Noriday 28 Day [PF]

ANDROGENS

3-oxoandrosten (4) derivatives

▪ TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

testosterone 5% (50 mg/mL) cream, 50 mL

10378F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	107.54	31.60	AndroForte 5 [LX]

▪ TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

8830R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	78.96	31.60	Testogel [HB]

testosterone 2% (23 mg/actuation) gel, 56 actuations

11740X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	84.41	31.60	Testavan [IX]

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

10380H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	4	..	78.96	31.60	Testogel [HB]

▪ TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Clinical criteria:

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Clinical criteria:

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Clinical criteria:

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

13983Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*146.01	31.60	Testogel [HB]

testosterone 2% (23 mg/actuation) gel, 56 actuations

14025E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*157.45	31.60	Testavan [IX]

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

13924W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	4	..	*146.01	31.60	Testogel [HB]

▪ TESTOSTERONE UNDECANOATE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10205D	1	1	..	94.43	31.60	[a] Reandron 1000 [AS]	[a] Testosterone ADVZ 1000 [BZ]

ESTROGENS

Natural and semisynthetic estrogens, plain

▪ ESTRADIOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

estradiol valerate 1 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1663M NP	1	2	..	16.59	18.04	Progynova [BN]

estradiol 2 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8274L NP	1	2	..	19.66	21.11	Zumenon [GO]

estradiol valerate 2 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1664N NP	1	2	..	17.91	19.36	Progynova [BN]

estradiol 10 microgram modified release pessary, 18

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10203B NP	1	2	..	30.02	31.47	[a] Estro-Pess [AS]	[a] Vagifem Low [NO]

▪ ESTRADIOL

Note Estradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8286D NP	‡1	5	..	25.63	27.08	Sandrena [OX]

estradiol 37.5 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8762E NP	‡1	5	..	30.28	31.60	[a] Estradiol Transdermal System (Sandoz, USA) [HX]	[a] Estradot 37.5 [SZ]

estradiol 75 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8764G NP	‡1	5	..	29.45	30.90	[a] Estradiol Transdermal System (Sandoz, USA) [HX]	[a] Estradot 75 [SZ]

estradiol 100 microgram/24 hours patch, 8

8312L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	26.82	28.27	Estraderm MX 100 [JU]

estradiol 100 microgram/24 hours patch, 8

8765H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	28.84	30.29	[a] Estradiol Transdermal System (Sandoz, USA) [HX]	[a] Estradot 100 [SZ]

estradiol 50 microgram/24 hours patch, 8

8140K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	24.99	26.44	Estraderm MX 50 [JU]

estradiol 50 microgram/24 hours patch, 8

8763F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	28.19	29.64	Estradot 50 [SZ]

estradiol 25 microgram/24 hours patch, 8

8311K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	24.99	26.44	Estraderm MX 25 [JU]

estradiol 25 microgram/24 hours patch, 8

8761D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	28.93	30.38	Estradot 25 [SZ]

▪ ESTRADIOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

estradiol valerate 1 mg tablet, 56

13872D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*19.73	21.18	Progynova [BN]

estradiol 2 mg tablet, 56

13931F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*25.87	27.32	Zumenon [GO]

estradiol valerate 2 mg tablet, 56

13980T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*22.37	23.82	Progynova [BN]

estradiol 10 microgram modified release pessary, 18

13978Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	2	..	*46.59	31.60	[a] Estro-Pess [AS]	[a] Vagifem Low [NO]

▪ ESTRADIOL

Note Estradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets

14026F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*37.81	31.60	Sandrena [OX]

▪ ESTRIOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

estriol 500 microgram pessary, 15

1771F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	26.27	27.72	Ovestin Ovula [AS]

estriol 0.1% (1 mg/g) cream, 15 g

1781R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	24.78	26.23	Ovestin [AS]

▪ ESTRIOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

estriol 500 microgram pessary, 15

14059Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	2	..	*39.09	31.60	Ovestin Ovula [AS]

estriol 0.1% (1 mg/g) cream, 15 g

13926Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	1	..	*36.11	31.60	Ovestin [AS]

PROGESTOGENS

Pregnen (4) derivatives

▪ MEDROXYPROGESTERONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

medroxyprogesterone acetate 10 mg tablet, 30

2321E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	20.33	21.78	[a] Ralovera [FZ]
		[B]6.70	27.03	21.78	[a] Provera [PF]

medroxyprogesterone acetate 5 mg tablet, 56

2323G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	18.94	20.39	[a] Ralovera [FZ]
		[B]4.58	23.52	20.39	[a] Provera [PF]

▪ MEDROXYPROGESTERONE

Restricted benefit

Endometriosis

medroxyprogesterone acetate 10 mg tablet, 100

2722G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	36.36	31.60	[a] Ralovera [FZ]
		[B]6.70	43.06	31.60	[a] Provera [PF]

▪ MEDROXYPROGESTERONE

Restricted benefit

Endometriosis

Clinical criteria:

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

medroxyprogesterone acetate 10 mg tablet, 100

13928C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*59.27	31.60	[a] Ralovera [FZ]
		[B]13.40	*72.67	31.60	[a] Provera [PF]

▪ MEDROXYPROGESTERONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

medroxyprogesterone acetate 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13849X NP	2	2	..	*27.21	28.66	[a] Ralovera [FZ]
			[B]13.40	*40.61	28.66	[a] Provera [PF]

medroxyprogesterone acetate 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13956M NP	2	2	..	*24.43	25.88	[a] Ralovera [FZ]
			[B]9.16	*33.59	25.88	[a] Provera [PF]

▪ PROGESTERONE

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

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

Authority required (STREAMLINED)

11835

Prevention of preterm birth

Clinical criteria:

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

progesterone 200 mg pessary, 42

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12598C NP MW	1	3	..	94.67	31.60	Utrogestan [HB]

▪ PROGESTERONE

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

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

Authority required (STREAMLINED)

11673

Prevention of preterm birth

Clinical criteria:

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

progesterone 200 mg pessary, 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12465C NP MW	3	3	..	*128.34	31.60	Oripro [ON]

Estren derivatives

▪ NORETHISTERONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

norethisterone 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2993M NP	1	2	..	35.67	31.60	Primolut N [BN]

▪ NORETHISTERONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

norethisterone 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13873E NP	2	2	..	*57.89	31.60	Primolut N [BN]

PROGESTOGENS AND ESTROGENS IN COMBINATION

Progestogens and estrogens, fixed combinations

▪ ESTRADIOL + NORETHISTERONE ACETATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8428N NP	‡1	5	..	34.73	31.60	Estalis continuous 50/250 [SZ]

estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8427M NP	‡1	5	..	33.73	31.60	Estalis continuous 50/140 [SZ]

▪ ESTRADIOL + NORETHISTERONE ACETATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13902Q NP	‡2	5	..	*54.01	31.60	Estalis continuous 50/140 [SZ]

Progestogens and estrogens, sequential preparations

▪ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8244X NP	‡1	5	..	24.19	25.64	Femoston 2/10 [GO]

estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10146B NP	‡1	5	..	24.19	25.64	Femoston 1/10 [GO]

▪ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13930E NP	‡2	5	..	*34.93	31.60	Femoston 2/10 [GO]

estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14024D NP	‡2	5	..	*34.93	31.60	Femoston 1/10 [GO]

▪ NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8

8425K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	41.14	31.60	Estalis sequi 50/140 [SZ]

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8

8426L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	43.29	31.60	Estalis sequi 50/250 [SZ]

▪ NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8

13932G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*68.83	31.60	Estalis sequi 50/140 [SZ]

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8

13981W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*73.13	31.60	Estalis sequi 50/250 [SZ]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

▪ CHORIOGONADOTROPIN ALFA

Restricted benefit

Infertility indications other than that of Assisted Reproductive Technology

Treatment criteria:

- Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule, **AND**
- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing, **AND**
- Must be treated by an obstetrician/gynaecologist; OR
- Must be treated by a specialist in reproductive endocrinology/infertility; OR
- Must be treated by a urogynaecologist; OR
- Must be treated by an endocrinologist; OR
- Must be treated by a urologist.

The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.

choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device

13300B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*220.03	31.60	Ovidrel [SG]

▪ FOLLITROPIN ALFA

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand, Bemfola or Ovaleap, is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form follitropin alfa cartridge (Ovaleap) and pharmaceutical benefits that have the form follitropin alfa single pen device (Gonal-f Pen), in the same corresponding strength, are equivalent for the purposes of substitution.

Where the Ovaleap brand is supplied, the separate pen device is to be supplied to the patient where required as it is not packaged with the cartridges. The pen device for the Ovaleap brand can be obtained by contacting the pharmaceutical wholesaler, or, the sponsor directly.

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin alfa 300 units (22 microgram)/0.5 mL injection, 0.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12769C	3	5	..	*301.17	31.60	[a] Ovaleap [TT]

follitropin alfa 450 units (33 microgram)/0.75 mL injection, 0.75 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12808D	3	5	..	*447.51	31.60	[a] Ovaleap [TT]

follitropin alfa 900 units (66 microgram)/1.5 mL injection, 1.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12778M	2	5	..	*747.89	31.60	[a] Ovaleap [TT]

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8713N	3	5	..	*301.17	31.60	[a] Gonal-f Pen [SG]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8714P	3	5	..	*447.51	31.60	[a] Gonal-f Pen [SG]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8715Q	2	5	..	*747.89	31.60	[a] Gonal-f Pen [SG]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10865W	3	1	..	*356.04	31.60	Bemfola [FX]

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10877L	3	1	..	*703.59	31.60	Bemfola [FX]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10876K	3	1	..	*1035.12	31.60	Bemfola [FX]

▪ FOLLITROPIN BETA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**

- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8565T	3	5	..	*317.94	31.60	[a] Puregon 300 IU/0.36 mL [OQ]	[a] Recagon [OV]

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8566W	2	5	..	*411.09	31.60	[a] Puregon 600 IU/0.72 mL [OQ]	[a] Recagon [OV]

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8871X	2	5	..	*607.01	31.60	[a] Puregon 900 IU/1.08 mL [OQ]	[a] Recagon [OV]

▪ HUMAN CHORIONIC GONADOTROPHIN

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Population criteria:

- Patient must be male.

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism.

Restricted benefit

Infertility

Population criteria:

- Patient must be male.

Clinical criteria:

- The condition must be associated with isolated luteinising hormone deficiency.

Restricted benefit

Combined deficiency of human growth hormone and gonadotrophins

Population criteria:

- Patient must be male.

Clinical criteria:

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

Restricted benefit

Hypogonadism or delayed puberty

Population criteria:

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

Clinical criteria:

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12905F	1	5	..	97.42	31.60	Brevactid 1500 I.E [DZ]

Ovulation stimulants, synthetic

▪ CLOMIFENE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Restricted benefit

Anovulatory infertility

Restricted benefit

Patients undergoing in-vitro fertilisation

clomifene citrate 50 mg tablet, 10

1211R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	35.13	31.60	Clomid [SW]

ANTIANDROGENS

Antiandrogens, plain

▪ CYPROTERONE

cyproterone acetate 100 mg tablet, 50

8019C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	61.27	31.60	[a] ANTERONE 100 [RW] [a] Pharmacor Cyproterone 100 [CR]	[a] Cyproterone Sandoz [HX]
		[B]1.21	62.48	31.60	[a] Androcur-100 [GH]	

cyproterone acetate 50 mg tablet, 50

1270W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*74.87	31.60	[a] ANTERONE 50 [RW] [a] Pharmacor Cyproterone 50 [CR]	[a] Cyproterone Sandoz [HX]
		[B]1.96	*76.83	31.60	[a] Androcur [GH]	

▪ CYPROTERONE

Restricted benefit

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

cyproterone acetate 100 mg tablet, 50

14022B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*109.09	31.60	[a] ANTERONE 100 [RW] [a] Pharmacor Cyproterone 100 [CR]	[a] Cyproterone Sandoz [HX]
		[B]2.42	*111.51	31.60	[a] Androcur-100 [GH]	

cyproterone acetate 50 mg tablet, 50

14023C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*137.39	31.60	[a] ANTERONE 50 [RW] [a] Pharmacor Cyproterone 50 [CR]	[a] Cyproterone Sandoz [HX]
		[B]4.12	*141.51	31.60	[a] Androcur [GH]	

▪ CYPROTERONE

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

5532

Moderate to severe androgenisation

Clinical criteria:

- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

Population criteria:

- Patient must be female.

Clinical criteria:

- Patient must not be pregnant.

cyproterone acetate 50 mg tablet, 20

1269T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	25.74	27.19	[a] ANTERONE 50 [RW] [a] Pharmacor Cyproterone 50 [CR]	[a] Cyproterone Sandoz [HX]

▪ CYPROTERONE

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

14868

Moderate to severe androgenisation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

Population criteria:

- Patient must be female.

Clinical criteria:

- Patient must not be pregnant.

cyproterone acetate 50 mg tablet, 20

13925X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*38.03	31.60	[a] ANTERONE 50 [RW] [a] Pharmacor Cyproterone 50 [CR]	[a] Cyproterone Sandoz [HX]

OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Progesterone receptor modulators

▪ MIFEPRISTONE (&) MISOPROSTOL

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14202

Termination of an intra-uterine pregnancy

Clinical criteria:

- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack

10211K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	390.73	31.60	MS-2 Step [XH]

NP MW

▪ UROLOGICALS

UROLOGICALS

Drugs for urinary frequency and incontinence

▪ OXYBUTYNIN

Restricted benefit

Detrusor overactivity

oxybutynin hydrochloride 5 mg tablet, 100

8039D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.65	19.10	Ditropan [SW]

NP

▪ OXYBUTYNIN

Restricted benefit

Detrusor overactivity

Clinical criteria:

- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

oxybutynin 3.9 mg/24 hours patch, 8

9454N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	32.28	31.60	Oxytrol [TT]

NP

▪ OXYBUTYNIN

Restricted benefit

Detrusor overactivity

Clinical criteria:

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

oxybutynin hydrochloride 5 mg tablet, 100

13957N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*21.85	23.30	Ditropan [SW]

NP

▪ OXYBUTYNIN

Restricted benefit

Detrusor overactivity

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

oxybutynin 3.9 mg/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13984B NP	‡2	5	..	*51.11	31.60	Oxytrol [TT]

▪ PROPANTHELINE

Restricted benefit

Detrusor overactivity

propantheline bromide 15 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1953T NP	2	5	..	*24.49	25.94	Pro-Banthine [RW]

▪ PROPANTHELINE

Restricted benefit

Detrusor overactivity

Clinical criteria:

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

propantheline bromide 15 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13927B NP	4	5	..	*35.51	31.60	Pro-Banthine [RW]

Other urologicals

▪ BICARBONATE

sodium bicarbonate 840 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9470K NP	1	2	..	21.65	23.10	Sodibic [AS]

▪ BICARBONATE

Restricted benefit

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

sodium bicarbonate 840 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13933H NP	2	2	..	*29.85	31.30	Sodibic [AS]

▪ PHENOXYBENZAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1166J NP	3	5	..	*678.33	31.60	Amdipharm Mercury (Australia) Pty Limited [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1862B NP	1	5	..	752.77	31.60	Dibenyline [GH]

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

▪ DUTASTERIDE + TAMSULOSIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6189

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

5490Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	31.36	31.60	[a] Doubluts [GC]
		[B]3.50	34.86	31.60	[a] Duodart 500ug/400ug [GK]

▪ DUTASTERIDE + TAMSULOSIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15004

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

13929D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*49.27	31.60	[a] Doubluts [GC]
		[B]7.00	*56.27	31.60	[a] Duodart 500ug/400ug [GK]

Testosterone-5-alpha reductase inhibitors

▪ DUTASTERIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6202

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

5468T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	29.82	31.27	[a] APO-Dutasteride [TX]
		[B]7.00	36.82	31.27	[a] Avodart [GK]

▪ DUTASTERIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15018

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

13900N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*46.19	31.60	[a] APO-Dutasteride [TX]
		[B]14.00	*60.19	31.60	[a] Avodart [GK]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

ACTH

TETRACOSACTIDE

Restricted benefit

Hypsarrhythmia and/or infantile spasms

tetracosactide 1 mg/mL modified release injection, 1 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2832C	5	5	..	*308.77	31.60	Synacthen Depot 1 mg/1 mL [IX]

Thyrotropin

THYROTROPIN ALFA

Restricted benefit

Ablation of thyroid remnant tissue

Clinical criteria:

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

thyrotropin alfa 900 microgram injection, 2 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2700D	1	..	..	1562.13	31.60	Thyrogen [GZ]

POSTERIOR PITUITARY LOBE HORMONES

Vasopressin and analogues

DESMOPRESSIN

Authority required (STREAMLINED)

5266

Cranial diabetes insipidus

desmopressin acetate 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8662X	3	5	..	*113.10	31.60	Minirin [FP]

DESMOPRESSIN

Authority required (STREAMLINED)

15012

Cranial diabetes insipidus

Clinical criteria:

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

desmopressin acetate 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13889B	6	5	..	*217.71	31.60	Minirin [FP]

DESMOPRESSIN

Note Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.

Authority required (STREAMLINED)

5266

Cranial diabetes insipidus

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8711L	2	5	..	*102.27	31.60	[a] Minirin Nasal Spray [FP]

desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12458Q	2	5	..	*232.69	31.60	[a] Desmopressin Nasal Spray USP (Apotex) [DZ]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

14945

Primary nocturnal enuresis

Clinical criteria:

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

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

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

Authority required (STREAMLINED)

15025

Primary nocturnal enuresis

Clinical criteria:

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

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

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

desmopressin 240 microgram sublingual wafer, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13890C NP	2	5	..	*140.55	31.60	Minirin Melt [FP]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

14972

Primary nocturnal enuresis

Clinical criteria:

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

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

No more than twice the maximum quantity will be authorised.

Authority required (STREAMLINED)

14842

Primary nocturnal enuresis

Clinical criteria:

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

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No more than twice the maximum quantity will be authorised.

desmopressin acetate 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13945Y NP	2	5	..	*79.89	31.60	Minirin [FP]

desmopressin 120 microgram sublingual wafer, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14004C NP	2	5	..	*87.49	31.60	Minirin Melt [FP]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

Authority required (STREAMLINED)

5413

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)

5295

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8663Y NP	1	5	..	46.67	31.60	Minirin [FP]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

Authority required (STREAMLINED)

5412

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)

5226

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin 120 microgram sublingual wafer, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9398P NP	1	5	..	50.47	31.60	Minirin Melt [FP]

desmopressin 240 microgram sublingual wafer, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8975J NP	1	5	..	76.36	31.60	Minirin Melt [FP]

▪ DESMOPRESSIN

Caution Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

5342

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)

5267

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8712M NP	‡1	5	..	57.86	31.60	[a] Minirin Nasal Spray [FP]

desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12459R NP	‡1	5	..	120.58	31.60	[a] Desmopressin Nasal Spray USP (Apotex) [DZ]

HYPOTHALAMIC HORMONES

Gonadotropin-releasing hormones

▪ NAFARELIN

Restricted benefit

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

Clinical criteria:

- The condition must be visually proven.

Restricted benefit

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

Clinical criteria:

- The condition must be visually proven, **AND**
- The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
- Patient must have had a recent bone density assessment.

The date of the bone density assessment must be recorded in the patient's medical records.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2962X	‡1	5	..	124.30	31.60	Synarel [PF]

▪ CORTICOSTEROIDS FOR SYSTEMIC USE

CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

Mineralocorticoids

▪ FLUDROCORTISONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

fludrocortisone acetate 100 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1433K NP	2	1	..	*35.15	31.60	[a] Florinef [AS]	[a] FLUDROCORTISONE MEDSURGE [DZ]

Glucocorticoids

▪ ABIRATERONE (&) METHYLPREDNISOLONE

Caution The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

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

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**

- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack

13263C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	1295.50	31.60	Yonsa Mpred [RA]

▪ ABIRATERONE (&) METHYLPREDNISOLONE

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

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

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

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

Authority required

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack

14078Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	1091.15	31.60	Yonsa Mpred [RA]

▪ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules

5034Y

DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	29.62	31.07	Celestone Chronodose [OQ]

▪ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Alopecia areata

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Granulomata

Clinical criteria:

- The condition must be dermal.

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

Restricted benefit

Lichen simplex chronicus

Restricted benefit

Chronic discoid lupus erythematosus

Restricted benefit

Necrobiosis lipoidica

Restricted benefit

Uveitis

betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules

2694T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	29.62	31.07	Celestone Chronodose [OQ]

▪ CORTISONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

cortisone acetate 25 mg tablet, 60

1247P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	25.92	27.37	Cortate [AS]

cortisone acetate 5 mg tablet, 50

1246N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	20.79	22.24	Cortate [AS]

▪ CORTISONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

cortisone acetate 25 mg tablet, 60

13862N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*38.39	31.60	Cortate [AS]

cortisone acetate 5 mg tablet, 50

13946B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*28.13	29.58	Cortate [AS]

▪ DEXAMETHASONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

dexamethasone 4 mg tablet, 30

2507Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	18.71	20.16	Dexmethsone [AS]

dexamethasone 500 microgram tablet, 30

1292B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	16.17	17.62	Dexmethsone [AS]

▪ DEXAMETHASONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

dexamethasone 500 microgram tablet, 30

14007F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*18.89	20.34	Dexmethsone [AS]

▪ HYDROCORTISONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

hydrocortisone 20 mg tablet, 60

1500Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	34.10	31.60	[a] Hydrocortisone Viatris 20 [AL]
		[B]3.00	37.10	31.60	[a] Hysone 20 [AF]

hydrocortisone 4 mg tablet, 50

1499X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	27.92	29.37	[a] Hydrocortisone Viatris 4 [AL]
		[B]3.00	30.92	29.37	[a] Hysone 4 [AF]

▪ HYDROCORTISONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

hydrocortisone 4 mg tablet, 50

13863P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*42.39	31.60	[a] Hydrocortisone Viatris 4 [AL]
		[B]6.00	*48.39	31.60	[a] Hysone 4 [AF]

▪ HYDROCORTISONE SODIUM SUCCINATE

hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

1501B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*23.27	24.72	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

3096Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	22.22	23.67	Solu-Cortef [PF]

▪ HYDROCORTISONE SODIUM SUCCINATE

Restricted benefit

For use in a hospital

hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

1510L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	..	..	*42.87	31.60	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

5118J DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	..	..	*42.87	31.60	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

1511M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	..	..	*66.03	31.60	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial

5119K DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	..	..	*66.03	31.60	Solu-Cortef [PF]

▪ METHYLPREDNISOLONE

methylprednisolone 1 g injection, 1 vial

5264C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	45.96	31.60	[a] Methylpred [AL]	[a] Solu-Medrol [PF]

▪ METHYLPREDNISOLONE

Restricted benefit

Local intra-articular or peri-articular infiltration

methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials

1928L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	28.10	29.55	[a] Depo-Medrol [PF]	[a] Depo-Nisolone [FZ]

▪ METHYLPREDNISOLONE

Restricted benefit

Local intra-articular or peri-articular infiltration

methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials

5148Y (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	28.10	29.55	[a] Depo-Medrol [PF]	[a] Depo-Nisolone [FZ]

▪ METHYLPREDNISOLONE

Note Pharmaceutical benefits that have the form methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial and pharmaceutical benefits that have the form methylprednisolone (as sodium succinate) 40 mg powder for injection, 1 vial are equivalent for the purposes of substitution.

methylprednisolone (as sodium succinate) 40 mg powder for injection, 1 vial

13736Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*114.32	31.60	[a] Solu-Medrone [LM]

methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial

11739W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*43.07	31.60	[a] Solu-Medrol [PF]

▪ PREDNISOLONE

prednisolone 1 mg tablet, 100

3152X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	16.56	18.01	[a] Predsolone [LN]
		[B]1.00	17.56	18.01	[a] Panafcortelone [AS]

prednisolone 25 mg tablet, 30

1916W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	17.85	19.30	Panafcortelone [AS]	Solone [IL]

prednisolone 5 mg tablet, 60

1917X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	17.00	18.45	Panafcortelone [AS]	Solone [IL]

▪ PREDNISOLONE

Restricted benefit

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

prednisolone 1 mg tablet, 100

13888Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*19.67	21.12	[a] Predsolone [LN]
		[B]2.00	*21.67	21.12	[a] Panafcortelone [AS]

prednisolone 5 mg tablet, 60

14045F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*20.55	22.00	Panafcortelone [AS]	Solone [IL]

▪ PREDNISOLONE SODIUM PHOSPHATE

prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL

8285C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	19.85	21.30	[a] PredMix [LN]
		[B]2.07	21.92	21.30	[a] Redipred [AS]

▪ PREDNISOLONE SODIUM PHOSPHATE

Restricted benefit

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

prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL

13837G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*26.25	27.70	[a] PredMix [LN]
		[B]4.14	*30.39	27.70	[a] Redipred [AS]

▪ PREDNISONE

prednisone 1 mg tablet, 100

1934T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	16.50	17.95	[a] Predsone [LN]
		[B]1.00	17.50	17.95	[a] Panafcort [AS]

prednisone 25 mg tablet, 30

1936X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	16.64	18.09	Panafcort [AS]	Sone [IL]

prednisone 5 mg tablet, 60

1935W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	16.91	18.36	Panafcort [AS]	Sone [IL]

▪ PREDNISONE

Restricted benefit

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

prednisone 1 mg tablet, 100

14043D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*19.55	21.00	[a] Predsone [LN]
		[B]2.00	*21.55	21.00	[a] Panafcort [AS]

prednisone 5 mg tablet, 60

13944X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*20.37	21.82	Panafcort [AS]	Sone [IL]

▪ TRIAMCINOLONE

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules

5233K DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	29.62	31.07	Kenacort-A10 [AS]

▪ TRIAMCINOLONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Alopecia areata

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Granulomata

Clinical criteria:

- The condition must be dermal.

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

Restricted benefit

Lichen simplex chronicus

Restricted benefit

Chronic discoid lupus erythematosus

Restricted benefit

Necrobiosis lipoidica

Restricted benefit

Psoriasis

triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2990J NP	1	..	..	29.62	31.07	Kenacort-A10 [AS]

THYROID THERAPY

THYROID PREPARATIONS

Thyroid hormones

LEVOTHYROXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

levothyroxine sodium 125 microgram tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12830G NP	1	1	..	26.89	28.34	Eltroxin [LT]

LEVOTHYROXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 75 microgram tablet, 2 x 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12960D NP	1	1	..	23.73	25.18	[a] LEVOXINE [RA]	[a] Thyrox [IX]

LEVOTHYROXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 100 microgram tablet, 2 x 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12968M NP	1	1	..	23.92	25.37	[a] LEVOXINE [RA]	[a] Thyrox [IX]

LEVOTHYROXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 50 microgram tablet, 2 x 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12969N NP	1	1	..	23.56	25.01	[a] LEVOXINE [RA]	[a] Thyrox [IX]

▪ LEVOTHYROXINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 200 microgram tablet, 2 x 100

12970P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	25.73	27.18	[a] LEVOXINE [RA]	[a] Thyrox [IX]

▪ LEVOTHYROXINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 200 microgram tablet, 200

2173J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	25.73	27.18	[a] APO-Levothyroxine [XT]	[a] Eutroxsig [LN]
					[a] Levothyroxine Lup [GQ]	[a] Levothyroxine Sandoz [SZ]
					[b] Eltroxin [LT]	[b] Levothox [AF]
		[B]1.31	27.04	27.18	[a] Oroxine [AS]	

▪ LEVOTHYROXINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 50 microgram tablet, 200

2174K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	23.56	25.01	[a] APO-Levothyroxine [XT]	[a] Eutroxsig [LN]
					[a] Levothyroxine Lup [GQ]	[a] Levothyroxine Sandoz [SZ]
					[b] Eltroxin [LT]	[b] Levothox [AF]
		[B]1.31	24.87	25.01	[a] Oroxine [AS]	

▪ LEVOTHYROXINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 100 microgram tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2175L NP	1	1	..	23.92	25.37	[a] APO-Levothyroxine [XT] [a] Levothyroxine Lup [GQ] [b] Eltroxin [LT]	[a] Eutroxsig [LN] [a] Levothyroxine Sandoz [SZ] [b] Levothox [AF]
			[B]1.31	25.23	25.37	[a] Oroxine [AS]	

▪ LEVOTHYROXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

levothyroxine sodium 75 microgram tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9287T NP	1	1	..	23.73	25.18	[a] APO-Levothyroxine [XT] [a] Levothyroxine Lup [GQ] [b] Eltroxin [LT]	[a] Eutroxsig [LN] [a] Levothyroxine Sandoz [SZ] [b] Levothox [AF]
			[B]1.32	25.05	25.18	[a] Oroxine [AS]	

▪ LIOTHYRONINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6382

Thyroid cancer

Authority required (STREAMLINED)

6410

Hypothyroidism

Clinical criteria:

- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

Authority required (STREAMLINED)

6475

Hypothyroidism

Clinical criteria:

- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

liothyronine sodium 20 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2318B NP	1	2	..	57.75	31.60	Tertroxin [AS]

▪ LIOTHYRONINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14843

Thyroid cancer

Clinical criteria:

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

Authority required (STREAMLINED)

14844

Hypothyroidism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

Authority required (STREAMLINED)

15038

Hypothyroidism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

liothyronine sodium 20 microgram tablet, 100

13966C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*102.05	31.60	Tertroxin [AS]

NP

ANTITHYROID PREPARATIONS

Thiouracils

▪ PROPYLTHIOURACIL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

propylthiouracil 50 mg tablet, 100

1955X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*44.93	31.60	PTU [FF]

NP

▪ PROPYLTHIOURACIL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

propylthiouracil 50 mg tablet, 100

13836F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*76.39	31.60	PTU [FF]

NP

Sulfur-containing imidazole derivatives

▪ CARBIMAZOLE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

carbimazole 5 mg tablet, 100

1153Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	2	..	*34.15	31.60	[a] Neo-Mercazole [GH] [a] WP Carbimazole [TN]	[a] THIRAZOL [NB]

NP

▪ CARBIMAZOLE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

carbimazole 5 mg tablet, 100

13967D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	2	..	*54.83	31.60	[a] Neo-Mercazole [GH] [a] WP Carbimazole [TN]	[a] THIRAZOL [NB]

NP

PANCREATIC HORMONES

GLYCOGENOLYTIC HORMONES

Glycogenolytic hormones

GLUCAGON HYDROCHLORIDE

glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

1449G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	51.10	31.60	GlucaGen Hypokit [NO]

NP

glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

5105Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	51.10	31.60	GlucaGen Hypokit [NO]

DP

CALCIUM HOMEOSTASIS

PARATHYROID HORMONES AND ANALOGUES

Parathyroid hormones and analogues

TERIPARATIDE

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

Authority required (STREAMLINED)

12492

Severe established osteoporosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

Authority required (STREAMLINED)

12270

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14093R	1	5	..	177.30	31.60	[a] Teriparatide Lupin [GQ]	[a] Terrosa [FX]

ANTI-PARATHYROID AGENTS

Calcitonin preparations

▪ CALCITONIN SALMON

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

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Symptomatic Paget disease of bone

Clinical criteria:

- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

Authority required

Hypercalcaemia

Clinical criteria:

- The treatment must be initiated in a hospital, **AND**
- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

calcitonin salmon 100 units/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2997R NP	3	5	..	*128.37	31.60	Miacalcic 100 [EU]

Other anti-parathyroid agents

▪ CINACALCET

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

10068

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment; OR
- Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

cinacalcet 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9157Y NP	1	5	..	38.96	31.60	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 60 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9158B NP	1	5	..	64.47	31.60	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9159C NP	1	5	..	89.97	31.60	[a] Cinacalcet Mylan [AF] [a] Pharmacor Cinacalcet [CR]	[a] Cinacalcet Viatris [AL]

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

TETRACYCLINES

Tetracyclines

DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

doxycycline 100 mg modified release capsule, 7

2708M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]1.54	17.69	17.60	[a] Mayne Pharma Doxycycline [YT]
		[B]2.95	19.10	17.60	[a] Doryx [YN]

doxycycline 100 mg modified release capsule, 7

3322W (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	[B]1.54	17.69	17.60	[a] Mayne Pharma Doxycycline [YT]
		[B]2.95	19.10	17.60	[a] Doryx [YN]

doxycycline 100 mg tablet, 7

2709N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	16.15	17.60	[a] APX-Doxycycline [TX] [a] Doxylin 100 [AF]	[a] Doxsig [RW]

doxycycline 100 mg tablet, 7

3321T (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.15	17.60	[a] APX-Doxycycline [TX] [a] Doxylin 100 [AF]	[a] Doxsig [RW]

doxycycline 100 mg tablet, 7

5082L (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	16.15	17.60	[a] Doxycycline Sandoz [HX]

doxycycline 100 mg tablet, 7

9105F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	16.15	17.60	[a] Doxycycline Sandoz [HX]

DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

Restricted benefit

Urethritis

doxycycline 100 mg modified release capsule, 21

2715X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	[B]3.22	24.74	22.97	[a] Mayne Pharma Doxycycline [YT]

doxycycline 100 mg tablet, 7

2714W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*21.54	22.99	[a] APX-Doxycycline [TX] [a] Doxylin 100 [AF]	[a] Doxsig [RW]

doxycycline 100 mg tablet, 7

9108J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*21.54	22.99	[a] Doxycycline Sandoz [HX]

doxycycline 100 mg tablet, 21

10176N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	21.52	22.97	[a] APX-Doxycycline [TX] [a] Doxylin 100 [AF]	[a] Doxsig [RW]

DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

Restricted benefit
Severe acne

doxycycline 100 mg modified release capsule, 7

10777F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	[B]6.16	*30.39	25.68	[a] Mayne Pharma Doxycycline [YT]
		[B]11.80	*36.03	25.68	[a] Doryx [YN]

doxycycline 100 mg tablet, 7

10779H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*24.23	25.68	[a] APX-Doxycycline [TX] [a] Doxylin 100 [AF]	[a] Doxsig [RW]

doxycycline 100 mg tablet, 7

10781K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*24.23	25.68	[a] Doxycycline Sandoz [HX]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

Restricted benefit
Pelvic inflammatory disease

doxycycline 100 mg modified release capsule, 7

2703G
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	[B]6.16	*30.39	25.68	[a] Mayne Pharma Doxycycline [YT]
		[B]11.80	*36.03	25.68	[a] Doryx [YN]

doxycycline 100 mg tablet, 7

2702F
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	..	..	*24.23	25.68	[a] APX-Doxycycline [TX] [a] Doxylin 100 [AF]	[a] Doxsig [RW]

doxycycline 100 mg tablet, 7

9107H
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*24.23	25.68	[a] Doxycycline Sandoz [HX]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

Restricted benefit
Bronchiectasis
Population criteria:
- Patient must be aged 8 years or older.

Restricted benefit
Chronic bronchitis
Population criteria:
- Patient must be aged 8 years or older.

Restricted benefit
Severe acne

doxycycline 50 mg modified release capsule, 25

2707L
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	[B]2.41	18.95	17.99	[a] Mayne Pharma Doxycycline [YT]
		[B]4.80	21.34	17.99	[a] Doryx [YN]

doxycycline 50 mg tablet, 25

2711Q
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.54	17.99	[a] APX-Doxycycline [TX] [a] Doxylin 50 [AF]	[a] Doxsig [RW]

doxycycline 50 mg tablet, 25

9106G
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	16.54	17.99	[a] Doxycycline Sandoz [HX]

▪ MINOCYCLINE

Caution There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

Restricted benefit

Severe acne

Clinical criteria:

- The condition must not be responding to other tetracyclines.

minocycline 50 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1616C NP	1	5	..	22.61	24.06	[a] Akamin 50 [AF]	[a] Minomycin-50 [AS]

BETA-LACTAM ANTIBACTERIALS, PENICILLINS

Penicillins with extended spectrum

▪ AMOXICILLIN

amoxicillin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3301R DP	1	..	..	16.17	17.62	[a] Alphamox 250 [AF] [a] APO-Amoxycillin [TX]	[a] AMILOXYN [RF] [a] Cilamox [AL]
			[B]4.68	20.85	17.62	[a] Amoxil [AS]	

amoxicillin 500 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3300Q DP	1	..	..	16.17	17.62	[a] Alphamox 500 [AF] [a] Amoxycillin generichealth 500 [GQ] [a] APO-Amoxycillin [TX] [a] Cilamox [AL]	[a] AMILOXYN [RF] [a] Amoxycillin Sandoz [SZ] [a] Blooms The Chemist Amoxicillin [BG] [a] NOUMED AMOXICILLIN [VO]
			[B]4.67	20.84	17.62	[a] Amoxil [AS]	

amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5225B DP	‡1	..	..	#19.70	21.57	Maxamox [SZ]

amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8705E NP	‡1	1	..	#19.70	21.57	Maxamox [SZ]

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1888J NP	‡1	1	[S]0.53	#23.37	24.71	Amoxil [AS]

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3310F DP	‡1	..	[S]0.53	#23.37	24.71	Amoxil [AS]

amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1886G NP	‡1	1	..	#19.43	21.30	[a] APO-Amoxycillin [TX]	[a] NOUMED AMOXICILLIN [VO]
			[B]4.55	#23.98	21.30	[a] Amoxil [AS]	

amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3302T DP	‡1	..	..	#19.43	21.30	[a] APO-Amoxycillin [TX]	[a] NOUMED AMOXICILLIN [VO]
			[B]4.55	#23.98	21.30	[a] Amoxil [AS]	

amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1887H NP	‡1	1	..	#19.43	21.30	[a] Amoxycillin Sandoz [SZ] [a] Cilamox [AL]	[a] APO-Amoxycillin [TX] [a] NOUMED AMOXICILLIN [VO]
			[B]4.32	#23.75	21.30	[a] Amoxil Forte [AS]	

amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3393N DP	‡1	..	..	#19.43	21.30	[a] Amoxycillin Sandoz [SZ] [a] Cilamox [AL]	[a] APO-Amoxycillin [TX] [a] NOUMED AMOXICILLIN [VO]
			[B]4.32	#23.75	21.30	[a] Amoxil Forte [AS]	

▪ AMOXICILLIN

Authority required (STREAMLINED)

10416

Community acquired pneumonia

Clinical criteria:

- Patient must have community acquired pneumonia.

amoxicillin 1 g tablet, 14

12002Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	16.37	17.82	[a] Amoxycillin Sandoz [BG]
		[B]1.00	17.37	17.82	[a] Maxamox [SZ]

▪ AMOXICILLIN

Restricted benefit

Chronic bronchitis

Clinical criteria:

- Patient must have acute exacerbations of the condition.

amoxicillin 1 g tablet, 14

8581P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	16.37	17.82	[a] Amoxycillin Sandoz [BG]
		[B]1.00	17.37	17.82	[a] Maxamox [SZ]

▪ AMOXICILLIN

Authority required

Infection suspected or proven to be due to a susceptible organism

Clinical criteria:

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

9714G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	#23.37	25.24	Amoxil [AS]

▪ AMOXICILLIN

Authority required (STREAMLINED)

10402

Infection

Clinical criteria:

- Patient must be a male with acute cystitis; OR
- Patient must have pyelonephritis; OR
- Patient must have a tooth avulsion; OR
- Patient must have salmonella enteritis; OR
- Patient must have community acquired pneumonia; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

amoxicillin 500 mg capsule, 20

11947T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*18.89	20.34	[a] Alphamox 500 [AF]	[a] AMILOXYN [RF]
					[a] Amoxycillin generichealth 500 [GQ]	[a] Amoxycillin Sandoz [SZ]
					[a] APO-Amoxycillin [TX]	[a] Blooms The Chemist Amoxicillin [BG]
					[a] Cilamox [AL]	[a] NOUMED AMOXICILLIN [VO]
		[B]9.34	*28.23	20.34	[a] Amoxil [AS]	

▪ AMOXICILLIN

Authority required (STREAMLINED)

10404

Infection

Clinical criteria:

- Patient must have a condition requiring prolonged oral antibiotic therapy.

amoxicillin 250 mg capsule, 20

11998L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*18.89	20.34	[a] Alphamox 250 [AF]	[a] AMILOXYN [RF]
					[a] APO-Amoxycillin [TX]	[a] Cilamox [AL]
		[B]9.36	*28.25	20.34	[a] Amoxil [AS]	

▪ AMOXICILLIN

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

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

amoxicillin 250 mg capsule, 20

1884E (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.17	17.62	[a] Alphamox 250 [AF]	[a] AMILOXYN [RF]
					[a] APO-Amoxycillin [TX]	[a] Cilamox [AL]
		[B]4.68	20.85	17.62	[a] Amoxil [AS]	

amoxicillin 500 mg capsule, 20

1889K (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.17	17.62	[a] Alphamox 500 [AF]	[a] AMILOXYN [RF]
					[a] Amoxycillin generichealth 500 [GQ]	[a] Amoxycillin Sandoz [SZ]
					[a] APO-Amoxycillin [TX]	[a] Blooms The Chemist Amoxicillin [BG]
					[a] Cilamox [AL]	[a] NOUMED AMOXICILLIN [VO]
		[B]4.67	20.84	17.62	[a] Amoxil [AS]	

Beta-lactamase sensitive penicillins

▪ BENZATHINE BENZYLPENICILLIN

benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes

11723B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	216.87	31.60	Bicillin L-A [PF]

benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes

11735P (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	216.87	31.60	Bicillin L-A [PF]

▪ BENZATHINE BENZYLPENICILLIN

Note Pharmaceutical benefits that have the brand Extencilline Benzathine Benzylpenicillin (France) may be substituted for pharmaceutical benefits that have the brand Bicillin L-A in case of shortage.

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13790T (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*511.97	31.60	[a] Extencilline Benzathine Benzylpenicillin (France) [YO]

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13816E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*511.97	31.60	[a] Extencilline Benzathine Benzylpenicillin (France) [YO]

benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

2267H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	335.98	31.60	[a] Bicillin L-A [PF]

benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

5027N (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	335.98	31.60	[a] Bicillin L-A [PF]

▪ BENZYLPENICILLIN

benzylpenicillin 600 mg injection, 1 vial

1775K (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	1	..	*72.87	31.60	BenPen [CS]

benzylpenicillin 600 mg injection, 1 vial

3398W (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*72.87	31.60	BenPen [CS]

benzylpenicillin 3 g injection, 1 vial

2647H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*109.27	31.60	BenPen [CS]

benzylpenicillin 3 g injection, 1 vial

3399X (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*109.27	31.60	BenPen [CS]

▪ PHENOXYMETHYLPENICILLIN

phenoxymethylpenicillin 250 mg capsule, 50

1789E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.58	19.03	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 250 mg capsule, 50

3363B DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.58	19.03	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 500 mg capsule, 50

2965C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	18.92	20.37	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 500 mg capsule, 50

3364C DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	18.92	20.37	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

5012T DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*25.17	26.62	Cilicaine V [AF]

phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

9143F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*25.17	26.62	Cilicaine V [AF]

phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL

5024K DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*#24.05	25.92	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL

8976K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*#24.05	25.92	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

5029Q DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*#25.51	27.38	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

8977L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*#25.51	27.38	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg tablet, 25

1787C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*18.85	20.30	Aspecillin VK [AF]

phenoxymethylpenicillin 250 mg tablet, 25

3360W DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*18.85	20.30	Aspecillin VK [AF]

phenoxymethylpenicillin 500 mg tablet, 25

3028J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*20.85	22.30	Aspecillin VK [AF]

phenoxymethylpenicillin 500 mg tablet, 25

3361X DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*20.85	22.30	Aspecillin VK [AF]

▪ PHENOXYMETHYLPENICILLIN

Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

Clinical criteria:

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

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13968E NP	2	5	..	*21.71	23.16	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14044E NP	4	5	..	*24.23	25.68	Aspecillin VK [AF]

▪ PHENOXYMETHYLPENICILLIN

Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

Clinical criteria:

- The treatment must be for prophylaxis.

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1705R NP	1	5	..	17.58	19.03	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1703P NP	2	5	..	*18.85	20.30	Aspecillin VK [AF]

Beta-lactamase resistant penicillins

▪ DICLOXACILLIN

Restricted benefit

Serious staphylococcal infection

dicloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5096F DP	1	..	..	18.17	19.62	[a] Dicloxacillin Mylan 250 [AL]	[a] DICLOXACILLIN VIATRIS 250 [MQ]
			[B]1.86	20.03	19.62	[a] Distaph 250 [AF]	

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5097G DP	1	..	..	21.56	23.01	[a] Dicloxacillin Mylan 500 [AL]	[a] DICLOXACILLIN VIATRIS 500 [MQ]
			[B]1.95	23.51	23.01	[a] Distaph 500 [AF]	

▪ DICLOXACILLIN

Restricted benefit

Serious staphylococcal infection

dicloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8121K NP MW	1	..	..	18.17	19.62	[a] Dicloxacillin Mylan 250 [AL]	[a] DICLOXACILLIN VIATRIS 250 [MQ]
			[B]1.86	20.03	19.62	[a] Distaph 250 [AF]	

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8122L NP MW	1	..	..	21.56	23.01	[a] Dicloxacillin Mylan 500 [AL]	[a] DICLOXACILLIN VIATRIS 500 [MQ]
			[B]1.95	23.51	23.01	[a] Distaph 500 [AF]	

▪ DICLOXACILLIN

Authority required (STREAMLINED)

6188

Osteomyelitis

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10790X	2	1	..	*29.67	31.12	[a] Dicloxacillin Mylan 500 [AL]	[a] DICLOXACILLIN VIATRIS 500 [MQ]
			[B]3.90	*33.57	31.12	[a] Distaph 500 [AF]	

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

flucloxacillin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1525G NP	1	1	..	22.60	24.05	Flucil [AS]

flucloxacillin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5095E DP	1	..	..	22.60	24.05	Flucil [AS]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1526H NP MW	1	..	..	17.73	19.18	[a] Flopen [AL] [a] Staphylex 250 [AF]	[a] Flopen Viatris [MQ]

flucloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1527J NP MW	1	..	..	22.15	23.60	[a] Flopen [AL] [a] Staphylex 500 [AF]	[a] Flopen Viatris [MQ]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5090X DP	1	..	..	17.73	19.18	[a] Flopen [AL] [a] Staphylex 250 [AF]	[a] Flopen Viatris [MQ]

flucloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5091Y DP	1	..	..	22.15	23.60	[a] Flopen [AL] [a] Staphylex 500 [AF]	[a] Flopen Viatris [MQ]

flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5257Q DP	‡1	..	..	#23.46	25.33	Flucil [LN]

flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5258R DP	‡1	..	..	#26.30	28.17	Flucil [LN]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9149M NP	‡1	1	..	#23.46	25.33	Flucil [LN]

flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9150N NP	‡1	1	..	#26.30	28.17	Flucil [LN]

▪ FLUCLOXACILLIN

Caution Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Authority required (STREAMLINED)

6169

Osteomyelitis

flucloxacillin 500 mg capsule, 24

10788T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*30.85	31.60	[a] Flopen [AL] [a] Staphylex 500 [AF]	[a] Flopen Viatris [MQ]

Combinations of penicillins, incl. beta-lactamase inhibitors

▪ AMOXICILLIN + CLAVULANIC ACID

Authority required (STREAMLINED)

10413

Infection

Clinical criteria:

- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have postpartum endometritis; OR
- Patient must have an exacerbation of bronchiectasis; OR
- Patient must have pyelonephritis; OR
- Patient must have pneumonia acquired in hospital or aged care; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

11933C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*20.09	21.54	[a] AlphaClav Duo Forte [AF]	[a] Alphaclav Duo Forte Viatris [AL]
						[a] AMCLAVOX DUO FORTE 875/125 [RW]	[a] AmoxyClav generichealth 875/125 [HQ]
						[a] APO-Amoxycillin and Clavulanic Acid [TX]	[a] APO-AMOXY/CLAV 875/125 [TW]
						[a] APX-Amoxicillin/Clavulanic Acid [XT]	[a] Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG]
						[a] Curam Duo Forte 875/125 [SZ]	
			[B]13.56	*33.65	21.54	[a] Augmentin Duo forte [AS]	

▪ AMOXICILLIN + CLAVULANIC ACID

Authority required (STREAMLINED)

10405

Infection

Clinical criteria:

- Patient must be a male with acute cystitis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

11941L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*19.49	20.94	[a] AlphaClav Duo [AF]	[a] AMCLAVOX DUO 500/125 [RW]
						[a] Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY]	[a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]
						[a] APO-AMOXY/CLAV 500/125 [TW]	[a] APX-Amoxicillin/Clavulanic Acid [XT]
						[a] Curam Duo 500/125 [SZ]	
			[B]10.82	*30.31	20.94	[a] Augmentin Duo [AS]	

▪ AMOXICILLIN + CLAVULANIC ACID

Caution Hepatotoxicity has been reported with this drug.

Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

1892N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	#19.43	21.30	Curam [SZ]

amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

8319W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	#19.43	21.30	[a] Curam Duo [SZ]
			[B]5.26	#24.69	21.30	[a] Augmentin Duo 400 [AS]

▪ AMOXICILLIN + CLAVULANIC ACID

Caution Hepatotoxicity has been reported with this drug.

Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5009P DP	‡1	..	..	#19.43	21.30	Curam [SZ]

amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5008N DP	1	..	..	16.47	17.92	[a] AlphaClav Duo [AF]	[a] AMCLAVOX DUO 500/125 [RW]
						[a] Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY]	[a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]
						[a] APO-AMOXY/CLAV 500/125 [TW]	[a] APX-Amoxicillin/Clavulanic Acid [XT]
						[a] Curam Duo 500/125 [SZ]	
			[B]5.41	21.88	17.92	[a] Augmentin Duo [AS]	

amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5006L DP	1	..	..	16.77	18.22	[a] AlphaClav Duo Forte [AF]	[a] Alphaclav Duo Forte Viatris [AL]
						[a] AMCLAVOX DUO FORTE 875/125 [RW]	[a] AmoxyClav generichealth 875/125 [HQ]
						[a] APO-Amoxycillin and Clavulanic Acid [TX]	[a] APO-AMOXY/CLAV 875/125 [TW]
						[a] APX-Amoxicillin/Clavulanic Acid [XT]	[a] Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG]
						[a] Curam Duo Forte 875/125 [SZ]	
			[B]6.78	23.55	18.22	[a] Augmentin Duo forte [AS]	

amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5011R DP	‡1	..	..	#19.43	21.30	[a] Curam Duo [SZ]
			[B]5.26	#24.69	21.30	[a] Augmentin Duo 400 [AS]

▪ AMOXICILLIN + CLAVULANIC ACID

Caution Hepatotoxicity has been reported with this drug.

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

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

Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1891M NP MW	1	..	..	16.47	17.92	[a] AlphaClav Duo [AF]	[a] AMCLAVOX DUO 500/125 [RW]
						[a] Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY]	[a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]
						[a] APO-AMOXY/CLAV 500/125 [TW]	[a] APX-Amoxicillin/Clavulanic Acid [XT]
						[a] Curam Duo 500/125 [SZ]	
			[B]5.41	21.88	17.92	[a] Augmentin Duo [AS]	

amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8254K NP	1	..	..	16.77	18.22	[a] AlphaClav Duo Forte [AF]	[a] Alphaclav Duo Forte Viatris [AL]
						[a] AMCLAVOX DUO FORTE 875/125 [RW]	[a] AmoxyClav generichealth 875/125 [HQ]
						[a] APO-Amoxycillin and Clavulanic Acid [TX]	[a] APO-AMOXY/CLAV 875/125 [TW]
						[a] APX-Amoxicillin/Clavulanic Acid [XT]	[a] Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG]
						[a] Curam Duo Forte 875/125 [SZ]	
			[B]6.78	23.55	18.22	[a] Augmentin Duo forte [AS]	

OTHER BETA-LACTAM ANTIBACTERIALS

First-generation cephalosporins

▪ CEFALEXIN

cefalexin 250 mg capsule, 20

3317N (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.17	17.62	[a] APO-Cephalexin [TX]	[a] Ibilex 250 [AF]
		[B]4.72	20.89	17.62	[a] Keflex [AS]	

cefalexin 500 mg capsule, 20

3318P (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.17	17.62	[a] APO-Cephalexin [TX]	[a] Blooms The Chemist Cefalexin [BG]
					[a] Cefalexin Sandoz [SZ]	[a] Cephalex 500 [CR]
					[a] Cephalexin generichealth [GQ]	[a] Ibilex 500 [AF]
					[a] NOUMED CEFALEXIN [VO]	
		[B]6.28	22.45	17.62	[a] Keflex [AS]	

cefalexin 125 mg/5 mL powder for oral liquid, 100 mL

3094W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	1	..	#19.43	21.30	[a] Cefalexin Sandoz [SZ]	[a] Ibilex 125 [AF]
		[B]4.66	#24.09	21.30	[a] Keflex [AS]	

cefalexin 125 mg/5 mL powder for oral liquid, 100 mL

3319Q (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	..	..	#19.43	21.30	[a] Cefalexin Sandoz [SZ]	[a] Ibilex 125 [AF]
		[B]4.66	#24.09	21.30	[a] Keflex [AS]	

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

3095X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	1	..	#19.53	21.40	[a] Cefalexin Sandoz [SZ]	[a] Ibilex 250 [AF]
		[B]6.01	#25.54	21.40	[a] Keflex [AS]	

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

3320R (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	..	..	#19.53	21.40	[a] Cefalexin Sandoz [SZ]	[a] Ibilex 250 [AF]
		[B]6.01	#25.54	21.40	[a] Keflex [AS]	

▪ CEFALEXIN

Authority required (STREAMLINED)

6188

Osteomyelitis

cefalexin 500 mg capsule, 20

10778G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	..	*18.89	20.34	[a] APO-Cephalexin [TX]	[a] Blooms The Chemist Cefalexin [BG]
					[a] Cefalexin Sandoz [SZ]	[a] Cephalex 500 [CR]
					[a] Cephalexin generichealth [GQ]	[a] Ibilex 500 [AF]
					[a] NOUMED CEFALEXIN [VO]	
		[B]12.56	*31.45	20.34	[a] Keflex [AS]	

▪ CEFALEXIN

Authority required (STREAMLINED)

10410

Infection

Clinical criteria:

- Patient must have a pin-site infection; OR
- Patient must have an infection following cardiac device insertion; OR
- Patient must have acute otitis externa; OR
- Patient must have streptococcal pharyngitis or tonsillitis; OR
- Patient must have mastitis; OR
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have acute rheumatic fever; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only.

cefalexin 500 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11934D NP MW	2	..	..	*18.89	20.34	[a] APO-Cephalexin [TX]	[a] Blooms The Chemist Cefalexin [BG]
						[a] Cefalexin Sandoz [SZ]	[a] Cephalex 500 [CR]
						[a] Cephalexin generichealth [GQ]	[a] Ibilex 500 [AF]
						[a] NOUMED CEFALEXIN [VO]	
			[B]12.56	*31.45	20.34	[a] Keflex [AS]	

▪ CEFALEXIN

Authority required (STREAMLINED)

10412

Infection

Clinical criteria:

- Patient must have impaired renal function, **AND**
- Patient must have a pin-site infection; OR
- Patient must have an infection following cardiac device insertion; OR
- Patient must have acute otitis externa; OR
- Patient must have streptococcal pharyngitis or tonsillitis; OR
- Patient must have mastitis; OR
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have acute rheumatic fever; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function.

cefalexin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11963P NP MW	2	..	..	*18.89	20.34	[a] APO-Cephalexin [TX]	[a] Ibilex 250 [AF]
			[B]9.44	*28.33	20.34	[a] Keflex [AS]	

▪ CEFALEXIN

Authority required (STREAMLINED)

4243

Prophylaxis of urinary tract infection

cefalexin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2655R	2	2	..	*18.89	20.34	[a] APO-Cephalexin [TX]	[a] Ibilex 250 [AF]
			[B]9.44	*28.33	20.34	[a] Keflex [AS]	

▪ CEFALEXIN

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

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

cefalexin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3058Y NP MW	1	..	..	16.17	17.62	[a] APO-Cephalexin [TX]	[a] Ibilex 250 [AF]
			[B]4.72	20.89	17.62	[a] Keflex [AS]	

cefalexin 500 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3119E NP MW	1	..	..	16.17	17.62	[a] APO-Cephalexin [TX]	[a] Blooms The Chemist Cefalexin [BG]
						[a] Cefalexin Sandoz [SZ]	[a] Cephalex 500 [CR]
						[a] Cephalexin generichealth [GQ]	[a] Ibilex 500 [AF]
						[a] NOUMED CEFALEXIN [VO]	
			[B]6.28	22.45	17.62	[a] Keflex [AS]	

▪ CEFAZOLIN

Restricted benefit

Cellulitis

cefazolin 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5477G NP	2	..	..	*20.85	22.30	Cefazolin-AFT [AE]

cefazolin 2 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12115P NP	1	..	..	46.68	31.60	[a] Cephazolin Alphapharm [AF]	[a] Cephazolin Viatris [AL]

▪ CEFAZOLIN

Restricted benefit

Cellulitis

cefazolin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1799Q NP	2	..	..	*22.07	23.52	Cefazolin-AFT [AE]

▪ CEFAZOLIN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefazolin 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1256D NP	2	..	..	*20.85	22.30	Cefazolin-AFT [AE]

cefazolin 2 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12118T NP	1	..	..	46.68	31.60	[a] Cephazolin Alphapharm [AF]	[a] Cephazolin Viatris [AL]

▪ CEFAZOLIN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefazolin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1797N NP	2	..	..	*22.07	23.52	Cefazolin-AFT [AE]

Second-generation cephalosporins

▪ CEFACLOR

Caution Serum sickness-like reactions have been reported with this drug, especially in children.

cefaclor 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2460L	‡1	1	..	#20.43	22.30	[a] Aclor 125 [MQ] [a] Keflor [AF]	[a] Cefaclor SUN [RA]
			[B]7.85	#28.28	22.30	[a] Ceclor [AL]	

cefaclor 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5046N DP	‡1	..	..	#20.43	22.30	[a] Aclor 125 [MQ] [a] Keflor [AF]	[a] Cefaclor SUN [RA]
			[B]7.85	#28.28	22.30	[a] Ceclor [AL]	

cefaclor 250 mg/5 mL powder for oral liquid, 75 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2461M	‡1	1	..	#20.43	22.30	[a] Aclor 250 [MQ] [a] Keflor [AF]	[a] Cefaclor SUN [RA]
			[B]7.85	#28.28	22.30	[a] Ceclor [AL]	

cefaclor 250 mg/5 mL powder for oral liquid, 75 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5047P DP	‡1	..	..	#20.43	22.30	[a] Aclor 250 [MQ] [a] Keflor [AF]	[a] Cefaclor SUN [RA]
			[B]7.85	#28.28	22.30	[a] Ceclor [AL]	

cefaclor 375 mg modified release tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1169M	1	1	..	17.37	18.82	[a] Karlor CD [MQ]	[a] Keflor CD [AF]
			[B]7.85	25.22	18.82	[a] Ceclor CD [AL]	

cefaclor 375 mg modified release tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5045M DP	1	..	..	17.37	18.82	[a] Karlor CD [MQ]	[a] Keflor CD [AF]
			[B]7.85	25.22	18.82	[a] Ceclor CD [AL]	

▪ CEFUROXIME

cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13643C	‡2	1	..	*#115.99	31.60	Zinnat (UK) [RQ]

cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13653N DP	‡2	..	..	*#115.99	31.60	Zinnat (UK) [RQ]

cefuroxime 250 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5052X DP	1	..	..	19.14	20.59	Pharmacor Cefuroxime [CR]

cefuroxime 250 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8292K	1	1	..	19.14	20.59	Pharmacor Cefuroxime [CR]

cefuroxime 250 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11227X	1	1	..	21.56	23.01	[a] Pharmacor Cefuroxime [CR]
			[B]3.90	25.46	23.01	[a] Zinnat [AS]

cefuroxime 250 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11228Y DP	1	..	..	21.56	23.01	[a] Pharmacor Cefuroxime [CR]
			[B]3.90	25.46	23.01	[a] Zinnat [AS]

Third-generation cephalosporins

▪ CEFOTAXIME

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

cefotaxime 1 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1768C DP	1	..	..	35.51	31.60	DBL Cefotaxime [PF]

▪ CEFOTAXIME

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefotaxime 1 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1758M NP	1	..	..	35.51	31.60	DBL Cefotaxime [PF]

▪ CEFTRIAXONE

Restricted benefit

Gonorrhoea

ceftriaxone 500 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9058R NP	1	..	..	16.15	17.60	Ceftriaxone-AFT [AE]

▪ CEFTRIAXONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 500 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1783W NP	5	..	..	*26.92	28.37	Ceftriaxone-AFT [AE]

▪ CEFTRIAXONE

Note Pharmaceutical benefits that have the form ceftriaxone 1 g injection, 5 vials and pharmaceutical benefits that have the form ceftriaxone 1 g injection, 10 vials are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1788D NP	1	..	..	27.17	28.62	[a] Ceftriaxone Viatris [AL]

ceftriaxone 1 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12114N NP	0.5	..	..	*32.61	31.60	[a] Ceftriaxone Viatris [AL]

▪ CEFTRIAXONE

Note Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 2 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11169W NP	1	..	..	27.28	28.73	[a] Ceftriaxone Viatris [AL]

ceftriaxone 2 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12112L NP	0.5	..	..	*32.74	31.60	[a] Ceftriaxone Viatris [AL]

Fourth-generation cephalosporins

▪ CEFEPIME

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Febrile neutropenia

cefepime 2 g injection, 1 vial

8316Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*56.47	31.60	Cefepime Kabi [PK]

cefepime 1 g injection, 1 vial

8315P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*53.57	31.60	Cefepime Kabi [PK]

SULFONAMIDES AND TRIMETHOPRIM

Trimethoprim and derivatives

▪ TRIMETHOPRIM

trimethoprim 300 mg tablet, 7

2922T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	16.15	17.60	[a] Trimethoprim Viatris [MQ]
		[B]2.76	18.91	17.60	[a] Alprim [AF]
		[B]3.98	20.13	17.60	[a] Triprim [RW]

▪ TRIMETHOPRIM

Authority required (STREAMLINED)

4243

Prophylaxis of urinary tract infection

trimethoprim 300 mg tablet, 7

2666H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*18.85	20.30	[a] Trimethoprim Viatris [MQ]
		[B]5.52	*24.37	20.30	[a] Alprim [AF]
		[B]7.96	*26.81	20.30	[a] Triprim [RW]

▪ TRIMETHOPRIM

Restricted benefit

Prostatitis

trimethoprim 300 mg tablet, 7

10785P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*24.23	25.68	[a] Trimethoprim Viatris [MQ]
		[B]11.04	*35.27	25.68	[a] Alprim [AF]
		[B]15.92	*40.15	25.68	[a] Triprim [RW]

Combinations of sulfonamides and trimethoprim, incl. derivatives

▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

3103H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	21.76	23.21	Septrin [RW]

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

3391L (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.76	23.21	Septrin [RW]

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

2951H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	16.15	17.60	[a] Bactrim DS [XO]	[a] Resprim Forte [AF]
		[B]4.17	20.32	17.60	[a] Septrin Forte [RW]	

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

3390K (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.15	17.60	[a] Bactrim DS [XO]	[a] Resprim Forte [AF]
		[B]4.17	20.32	17.60	[a] Septrin Forte [RW]	

▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.

Authority required (STREAMLINED)

6201

Prophylaxis of Pneumocystis jiroveci pneumonia

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

10784N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	2	..	*21.54	22.99	[a] Bactrim DS [XO]	[a] Resprim Forte [AF]
		[B]12.51	*34.05	22.99	[a] Septrin Forte [RW]	

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

▪ AZITHROMYCIN

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

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

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	#28.96	30.83	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	17.85	19.30	[a] APO-Azithromycin [TX]	[a] Azithromycin Mylan [AF]
					[a] Azithromycin Sandoz [SZ]	[a] Azithromycin Viatris [AL]
					[a] ZITHRO [RW]	[a] Zithromax [PF]

▪ AZITHROMYCIN

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

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

Restricted benefit

Urethritis

Clinical criteria:

- The condition must be uncomplicated and due to Chlamydia trachomatis.

Restricted benefit

Cervicitis

Clinical criteria:

- The condition must be uncomplicated and due to Chlamydia trachomatis.

azithromycin 500 mg tablet, 2

8200N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.85	19.30	[a] APO-Azithromycin [TX]	[a] Azithromycin Mylan [AF]
					[a] Azithromycin Sandoz [SZ]	[a] Azithromycin Viatris [AL]
					[a] ZITHRO [RW]	[a] Zithromax [PF]

▪ CLARITHROMYCIN

clarithromycin 250 mg tablet, 14

8318T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	17.12	18.57	[a] Clarithro 250 [RW]	[a] Clarithromycin Sandoz [SZ]
					[a] Kalixocin [AF]	[a] NOUMED CLARITHROMYCIN [VO]
		[B]3.33	20.45	18.57	[a] Klacid [GO]	

▪ CLARITHROMYCIN

Restricted benefit

Bordetella pertussis

Restricted benefit

Atypical mycobacterial infections

clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL

9192T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	#32.63	31.60	Klacid [GO]

▪ ERYTHROMYCIN

erythromycin 250 mg enteric capsule, 25

1404X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	23.64	25.09	Mayne Pharma Erythromycin [YT]

NP

erythromycin 250 mg enteric capsule, 25

3325B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.64	25.09	Mayne Pharma Erythromycin [YT]

DP

▪ ERYTHROMYCIN

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.

erythromycin 250 mg enteric capsule, 25

10780J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*33.83	31.60	Mayne Pharma Erythromycin [YT]

▪ ERYTHROMYCIN ETHYLSUCCINATE

erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

2424N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	#21.39	23.26	E-Mycin 200 [AF]

NP

erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

3334L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	#21.39	23.26	E-Mycin 200 [AF]

DP

erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL

2428T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	#22.63	24.50	E-Mycin 400 [AF]

NP

erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL

3337P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	#22.63	24.50	E-Mycin 400 [AF]

DP

▪ ROXITHROMYCIN

roxithromycin 150 mg tablet, 10

5260W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.48	17.93	[a] APO-Roxithromycin [TX] [a] Roxar 150 [RW]	[a] APX-Roxithromycin [TY] [a] Roxithromycin Sandoz [SZ]

DP

roxithromycin 300 mg tablet, 5

5261X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.48	17.93	[a] APO-Roxithromycin [TX] [a] Roxar 300 [RW]	[a] APX-Roxithromycin [TY] [a] Roxithromycin Sandoz [SZ]

DP

▪ ROXITHROMYCIN

Authority required (STREAMLINED)

10404

Infection

Clinical criteria:

- Patient must have a condition requiring prolonged oral antibiotic therapy.

roxithromycin 150 mg tablet, 10

12001P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*19.51	20.96	[a] APO-Roxithromycin [TX] [a] Roxar 150 [RW]	[a] APX-Roxithromycin [TY] [a] Roxithromycin Sandoz [SZ]

NP

roxithromycin 300 mg tablet, 5

11993F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*19.51	20.96	[a] APO-Roxithromycin [TX] [a] Roxar 300 [RW]	[a] APX-Roxithromycin [TY] [a] Roxithromycin Sandoz [SZ]

NP

▪ ROXITHROMYCIN

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

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

roxithromycin 150 mg tablet, 10

1760P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.48	17.93	[a] APO-Roxithromycin [TX] [a] Roxar 150 [RW]	[a] APX-Roxithromycin [TY] [a] Roxithromycin Sandoz [SZ]

roxithromycin 300 mg tablet, 5

8016X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.48	17.93	[a] APO-Roxithromycin [TX] [a] Roxar 300 [RW]	[a] APX-Roxithromycin [TY] [a] Roxithromycin Sandoz [SZ]

Lincosamides

▪ CLINDAMYCIN

Restricted benefit

Gram-positive coccal infections

Clinical criteria:

- The condition must not be able to be safely and effectively treated with a penicillin.

clindamycin 150 mg capsule, 24

5057E (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.94	19.39	[a] APO-Clindamycin [TX] [a] Clindamycin LU [XT] [a] Dalacin C [PF]	[a] Calindamin [RW] [a] Clindamyk [AF]

▪ CLINDAMYCIN

Restricted benefit

Gram-positive coccal infections

Clinical criteria:

- The condition must not be able to be safely and effectively treated with a penicillin.

clindamycin 150 mg capsule, 24

3138E (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	..	*22.43	23.88	[a] APO-Clindamycin [TX] [a] Clindamycin LU [XT] [a] Dalacin C [PF]	[a] Calindamin [RW] [a] Clindamyk [AF]

▪ LINCOMYCIN

Note Pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL vials and pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules are equivalent for the purposes of substitution.

lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

2530E (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	60.78	31.60	[a] Lincocin [PF]

lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

5144R (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	60.78	31.60	[a] Lincocin [PF]

lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules

11366F (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	60.78	31.60	[a] LINCOMYCIN SXP [XN]

lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules

11380Y (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	60.78	31.60	[a] LINCOMYCIN SXP [XN]

AMINOGLYCOSIDE ANTIBACTERIALS

Other aminoglycosides

▪ GENTAMICIN

gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules

2824P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	24.98	26.43	Pfizer Australia Pty Ltd [PF]

▪ TOBRAMYCIN

Restricted benefit

Pseudomonas aeruginosa infection

Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

tobramycin 500 mg/5 mL injection, 10 x 5 mL vials

9480Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	193.82	31.60	Tobra-Day [FF]

▪ TOBRAMYCIN

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

Authority required (STREAMLINED)
5520
Proven Pseudomonas aeruginosa infection
Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

5442K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	474.48	31.60	[a] Tobi [GO] [a] Tobramycin WKT [JU]	[a] TOBRAMYCIN SUN [RA]

▪ TOBRAMYCIN

Restricted benefit
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
Restricted benefit
Septicaemia, suspected
Restricted benefit
Septicaemia, proven

tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

1356J

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*39.91	31.60	Tobramycin Viatris [AL]

tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

8872Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*48.43	31.60	Pfizer Australia Pty Ltd [PF]

▪ TOBRAMYCIN

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

Authority required (STREAMLINED)
15040
Proven Pseudomonas aeruginosa infection
Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

14006E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	2	..	*940.51	31.60	[a] Tobi [GO] [a] Tobramycin WKT [JU]	[a] TOBRAMYCIN SUN [RA]

▪ TOBRAMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
4456
Proven Pseudomonas aeruginosa infection
Treatment Phase: Initial treatment
Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**

- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

Population criteria:

- Patient must be 6 years of age or older.

tobramycin 28 mg powder for inhalation, 224 capsules

10066T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	2418.38	31.60	TOBI podhaler [GO]

▪ TOBRAMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4513

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

Population criteria:

- Patient must be 6 years of age or older.

tobramycin 28 mg powder for inhalation, 224 capsules

10074F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2418.38	31.60	TOBI podhaler [GO]

▪ TOBRAMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15036

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

Population criteria:

- Patient must be 6 years of age or older.

tobramycin 28 mg powder for inhalation, 224 capsules

13965B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4728.31	31.60	TOBI podhaler [GO]

QUINOLONE ANTIBACTERIALS

Fluoroquinolones

▪ CIPROFLOXACIN

Authority required

Respiratory tract infection

Clinical criteria:

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

- Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

ciprofloxacin 500 mg tablet, 14

1209P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.87	19.32	[a] APO-Ciprofloxacin [TX] [a] C-Flox 500 [AL] [a] Ciprofloxacin Sandoz [SZ] [a] NOUMED CIPROFLOXACIN [VO]	[a] APX-Ciprofloxacin [TY] [a] Cifran [RA] [a] Ciprol 500 [RW]

ciprofloxacin 750 mg tablet, 14

1210Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	18.85	20.30	[a] APO-Ciprofloxacin [TX] [a] C-Flox 750 [AL] [a] Ciprol 750 [RW]	[a] APX-Ciprofloxacin [TY] [a] Ciprofloxacin Sandoz [SZ] [a] NOUMED CIPROFLOXACIN [VO]

▪ CIPROFLOXACIN

Authority required

Respiratory tract infection

Clinical criteria:

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

- Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Gonorrhoea

ciprofloxacin 250 mg tablet, 14

1208N NP

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		..	..	17.35	18.80	[a] APO-Ciprofloxacin [TX] [a] C-Flox 250 [AL] [a] Ciprol 250 [RW]	[a] APX-Ciprofloxacin [TY] [a] Ciprofloxacin Sandoz [SZ]

▪ NORFLOXACIN

Authority required

Acute bacterial enterocolitis

Authority required

Complicated urinary tract infection

norfloxacin 400 mg tablet, 14

3010K NP

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	..	17.37	18.82	[a] APO-Norfloxacin [TX] [a] Roxin [RW]	[a] Nufloxib [AF]

OTHER ANTIBACTERIALS

Glycopeptide antibacterials

▪ VANCOMYCIN

Restricted benefit

Endocarditis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

2269K

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1		..	..	19.91	21.36	Vancomycin Alphapharm [AF]

vancomycin 500 mg injection, 1 vial

3130R

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2		..	..	*22.07	23.52	Vancomycin Alphapharm [AF]

▪ VANCOMYCIN

Restricted benefit

Endocarditis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

5083M DP

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1		..	..	19.91	21.36	Vancomycin Alphapharm [AF]

vancomycin 500 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3323X DP	2	..	..	*22.07	23.52	Vancomycin Alphapharm [AF]

▪ VANCOMYCIN

Restricted benefit

Endophthalmitis

Restricted benefit

Infection

Clinical criteria:

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

vancomycin 1 g injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2270L	3	..	..	*32.82	31.60	Vancomycin Alphapharm [AF]

vancomycin 500 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3131T	5	..	..	*34.97	31.60	Vancomycin Alphapharm [AF]

Steroid antibacterials

▪ FUSIDATE

Restricted benefit

Serious staphylococcal infections

Clinical criteria:

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

sodium fusidate 250 mg tablet, 36

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2312Q	1	1	..	101.29	31.60	Fucidin [LO]

▪ FUSIDATE

Authority required (STREAMLINED)

6133

Osteomyelitis

Clinical criteria:

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

sodium fusidate 250 mg tablet, 36

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10782L	2	1	..	*192.91	31.60	Fucidin [LO]

Imidazole derivatives

▪ METRONIDAZOLE

metronidazole 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1642K NP	‡1	..	..	30.42	31.60	Flagyl [SW]

metronidazole 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5157K DP	‡1	..	..	30.42	31.60	Flagyl [SW]

metronidazole 200 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1636D NP	1	1	..	16.37	17.82	Metrogyl 200 [AF]

metronidazole 200 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3339R DP	1	..	..	16.37	17.82	Metrogyl 200 [AF]

metronidazole 200 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1630T NP	‡1	..	..	24.24	25.69	Flagyl S [SW]

metronidazole 200 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3341W DP	‡1	..	..	24.24	25.69	Flagyl S [SW]

▪ METRONIDAZOLE

Restricted benefit

Anaerobic infections

metronidazole 400 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1621H NP	1	1	..	17.14	18.59	[a] Metrogyl 400 [AF]
			[B]2.50	19.64	18.59	[a] Flagyl [SW]

▪ METRONIDAZOLE

Restricted benefit

Anaerobic infections

metronidazole 400 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5155H DP	1	..	..	17.14	18.59	[a] Metrogyl 400 [AF]
			[B]2.50	19.64	18.59	[a] Flagyl [SW]

Nitrofuran derivatives

▪ NITROFURANTOIN

Caution Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

nitrofurantoin 100 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1693D NP MW	1	1	..	27.45	28.90	[a] ARX-Nitrofurantoin [XT]	[a] Nitrofurantoin BNM [BZ]

nitrofurantoin 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1692C NP MW	1	1	..	23.43	24.88	[a] ARX-Nitrofurantoin [XT]	[a] Nitrofurantoin BNM [BZ]

Other antibacterials

▪ METHENAMINE HIPPURATE

methenamine hippurate 1 g tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3124K NP	1	5	..	31.76	31.60	[a] Hiprex [IL]	[a] Uramet [AS]

▪ METHENAMINE HIPPURATE

Restricted benefit

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

methenamine hippurate 1 g tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14005D NP	2	5	..	*50.07	31.60	[a] Hiprex [IL]	[a] Uramet [AS]

▪ ANTIMYCOTICS FOR SYSTEMIC USE

ANTIMYCOTICS FOR SYSTEMIC USE

Triazole and tetrazole derivatives

▪ FLUCONAZOLE

Note Not for use in vulvovaginal candida infections.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6002

Cryptococcal meningitis

Authority required (STREAMLINED)

5978

Cryptococcal meningitis

Clinical criteria:

- The treatment must be maintenance therapy, **AND**

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6023

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

5989

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6030

Oropharyngeal candidiasis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

Authority required (STREAMLINED)

7898

Fungal infection

Clinical criteria:

- The condition must be serious or life-threatening.

fluconazole 100 mg capsule, 28

1472L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	25.86	27.31	[a] Dizole 100 [AF] [a] Ozole [RA]	[a] Fluconazole Sandoz [SZ]
		[B]4.25	30.11	27.31	[a] Diflucan [PF]	

fluconazole 200 mg capsule, 28

1475P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.62	31.60	[a] Dizole 200 [AF] [a] Fluconazole Sandoz [SZ] [a] Ozole [RA]	[a] Fluconazole APOTEX [GX] [a] Fluzole 200 [RW]
		[B]7.16	44.78	31.60	[a] Diflucan [PF]	

fluconazole 50 mg capsule, 28

1471K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.84	21.29	[a] Dizole 50 [AF] [a] Ozole [RA]	[a] Fluconazole Sandoz [SZ]
		[B]3.59	23.43	21.29	[a] Diflucan [PF]	

▪ FLUCONAZOLE

Note Not for use in vulvovaginal candida infections.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6006

Cryptococcal meningitis

Clinical criteria:

- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)

6045

Cryptococcal meningitis

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)

6031

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)

6046

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)

6032

Oropharyngeal candidiasis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)

7934

Fungal infection

Clinical criteria:

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

fluconazole 50 mg/5 mL powder for oral liquid, 35 mL

5446P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	#70.06	31.60	Diflucan [PF]

▪ ITRACONAZOLE

Note Not for use in vulvovaginal candida infections.

Note One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole capsules. The recommended dose for Lozanoc is therefore half the recommended dose for conventional itraconazole capsules. Lozanoc 50 mg capsules and conventional itraconazole 100 mg capsules are not interchangeable.

Note Not for use in superficial mycoses

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6022

Systemic aspergillosis

Authority required (STREAMLINED)

6005

Systemic sporotrichosis

Authority required (STREAMLINED)

6057

Systemic histoplasmosis

Authority required (STREAMLINED)

5988

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Authority required (STREAMLINED)

6037

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Authority required (STREAMLINED)

6016

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6035

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

itraconazole 100 mg capsule, 60

8196J

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	118.22	31.60	[a] APO-Itraconazole [TX] [a] ITRANOX [RW]	[a] Itracap [AF]

itraconazole 50 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10732W NP	1	5	..	118.22	31.60	Lozanoc [YN]

▪ POSACONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Invasive aspergillosis

Clinical criteria:

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

Authority required

Fungal infection

Clinical criteria:

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

posaconazole 100 mg modified release tablet, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10460M NP	1	..	..	162.67	31.60	[a] Pharmacor Posaconazole [CR] [a] POSACONAZOLE DR.REDDY'S [RZ] [a] Posaconazole Sandoz [SZ]	[a] Posaconazole ARX [XT] [a] Posaconazole Juno [JU]

▪ VORICONAZOLE

Note For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

voriconazole 40 mg/mL powder for oral liquid, 70 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10168E NP	1	..	..	#507.29	31.60	Vfend [PF]

voriconazole 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10198R NP	1	..	..	306.56	31.60	[a] Voriconazole Sandoz [SZ] [a] Vzole [RW]	[a] Vttack [AF]

voriconazole 50 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10173K NP	1	..	..	84.43	31.60	[a] Voriconazole Sandoz [SZ] [a] Vzole [RW]	[a] Vttack [AF]

▪ VORICONAZOLE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by Scedosporium species; OR
- The condition must caused by Fusarium species.

Authority required

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9364W NP	1	2	..	306.56	31.60	[a] Voriconazole Sandoz [SZ] [a] Vzole [RW]	[a] Vttack [AF]

voriconazole 50 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9363T NP	1	2	..	84.43	31.60	[a] Voriconazole Sandoz [SZ] [a] Vzole [RW]	[a] Vttack [AF]

▪ VORICONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by Scedosporium species; OR
- The condition must caused by Fusarium species.

Authority required

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 40 mg/mL powder for oral liquid, 70 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9452L NP	1	..	..	#507.29	31.60	Vfend [PF]

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFAMPICIN

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Mycobacterium ulcerans infection (Buruli ulcer)

Clinical criteria:

- The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer.

rifampicin 150 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12200D NP	12	..	..	*232.47	31.60	Rimycin 150 [AF]

rifampicin 150 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12190N NP	1	..	..	195.19	31.60	Rimycin 150 [AF]

rifampicin 300 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12189M NP	12	..	..	*110.79	31.60	Rimycin 300 [AF]

rifampicin 300 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12215X NP	1	..	..	94.53	31.60	Rimycin 300 [AF]

Hydrazides

ISONIAZID

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

isoniazid 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1554T NP	1	2	..	21.73	23.18	Arrow Pharma Pty Ltd [RW]

DRUGS FOR TREATMENT OF LEPRA

Drugs for treatment of lepra

DAPSONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

dapsone 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1272Y NP	1	1	..	401.14	31.60	Link Medical Products Pty Ltd [LM]

dapsone 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8801F NP	1	1	..	328.45	31.60	Link Medical Products Pty Ltd [LM]

▪ RIFAMPICIN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Leprosy
Population criteria:
- Patient must be an adult.

rifampicin 150 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1982H NP	1	..	..	195.19	31.60	Rimycin 150 [AF]

rifampicin 300 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1983J NP	1	..	..	94.53	31.60	Rimycin 300 [AF]

▪ RIFAMPICIN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Meningococcal disease
Clinical criteria:
- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; OR
- Patient must be in close contact with people who have the disease.

Restricted benefit
Haemophilus influenzae type B
Clinical criteria:
- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

rifampicin 150 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1981G NP	1	..	..	31.24	31.60	Rimycin 150 [AF]

rifampicin 300 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1984K NP	1	..	..	21.57	23.02	Rimycin 300 [AF]

rifampicin 100 mg/5 mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8025J NP	‡1	..	..	26.60	28.05	Rifadin [SW]

▪ ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

▪ ACICLOVIR

Note Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)
5942
Recurrent moderate to severe genital herpes
Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

aciclovir 200 mg tablet, 90

1007B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	34.90	31.60	[a] Aciclovir APOTEX [TY] [a] Aciclovir Sandoz [HX] [a] ARX-ACICLOVIR [XT]	[a] Aciclovir GH [GQ] [a] APO-Aciclovir [TX]

▪ ACICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5967

Herpes zoster

Clinical criteria:

- The treatment must be administered within 72 hours of the onset of the rash.

Authority required (STREAMLINED)

5959

Herpes zoster ophthalmicus

aciclovir 800 mg tablet, 35

1052J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	39.39	31.60	[a] Aciclovir APOTEX [TY] [a] APO-Aciclovir [TX]	[a] Aciclovir Sandoz [HX]

▪ ACICLOVIR

Note Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

Note For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5936

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

aciclovir 200 mg tablet, 25

1003T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*25.39	26.84	[a] Aciclovir Sandoz [HX]

aciclovir 200 mg tablet, 50

1555W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	25.37	26.82	[a] Aciclovir APOTEX [TY]	[a] APO-Aciclovir [TX]

▪ FAMCICLOVIR

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5937

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 250 mg tablet, 20

2274Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	32.11	31.60	[a] APO-Famciclovir [TX] [a] Favic 250 [RW]	[a] Famvir [IX]

▪ FAMCICLOVIR

Note Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5937

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 125 mg tablet, 40

8092X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	32.11	31.60	[a] APO-Famciclovir [TX] [a] Favic 125 [RW]	[a] Famvir [IX]

▪ FAMCICLOVIR

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5971

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 250 mg tablet, 56

8217L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	65.69	31.60	[a] APO-Famciclovir [TX] [a] Famvir [IX]	[a] Ezovir [AF] [a] Favic 250 [RW]

▪ FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5951

Herpes zoster

Clinical criteria:

- The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 250 mg tablet, 21

8002E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	33.05	31.60	[a] APO-Famciclovir [TX] [a] Famvir [IX]	[a] Ezovir [AF] [a] Favic 250 [RW]

▪ FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5943

Herpes zoster

Clinical criteria:

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 500 mg tablet, 30

8897G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	41.46	31.60	[a] APO-Famciclovir [TX] [a] Favic 500 [RW]	[a] Famvir [IX]

▪ FAMCICLOVIR

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Authority required (STREAMLINED)

5954

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Clinical criteria:

- Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)

5947

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

Clinical criteria:

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)

5948

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)

5949

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

- Patient must have HIV infection, **AND**
- Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 500 mg tablet, 56

8896F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	65.73	31.60	[a] APO-Famciclovir [TX] [a] Famvir [IX]	[a] Ezovir [AF] [a] Favic 500 [RW]

▪ MOLNUPIRAVIR

Note Details of the Liverpool COVID-19 Drug interaction checker can be found at: https://www.covid19-druginteractions.org/checker

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15050

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

Authority required (STREAMLINED)

15062

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**

- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

Authority required (STREAMLINED)

15055

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care

2. The patient has disability with multiple comorbidities and/or frailty

3. Neurological conditions, including stroke and dementia and demyelinating conditions

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease

5. Heart failure, coronary artery disease, cardiomyopathies

6. Obesity (BMI greater than 30 kg/m^2)

7. Diabetes type I or II, requiring medication for glycaemic control

8. Renal impairment (eGFR less than 60mL/min)

9. Cirrhosis

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above

11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

Authority required (STREAMLINED)

15056

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,

2. The patient has disability with multiple comorbidities and/or frailty,

3. Neurological conditions, including stroke and dementia and demyelinating conditions,

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,

5. Heart failure, coronary artery disease, cardiomyopathies,

6. Obesity (BMI greater than 30 kg/m^2),

7. Diabetes type I or II, requiring medication for glycaemic control,

8. Renal impairment (eGFR less than 60mL/min),

9. Cirrhosis, or

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

molnupiravir 200 mg capsule, 40

12910L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1102.71	31.60	Lagevrio [MK]

▪ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5940

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 30

5480K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	26.36	27.81	[a] APX-Valaciclovir [TY]	[a] Shilova 500 [ZS]
					[a] Vaclovir [AF]	[a] Valaciclovir APOTEX [GX]
					[a] Valaciclovir generichealth [GQ]	[a] Valaciclovir RBX [RA]
					[a] Valaciclovir Sandoz [SZ]	[a] Valaciclovir SZ [HX]
					[a] Valacor 500 [CR]	[a] Zelitrex [RF]
		[B]2.43	28.79	27.81	[a] Valtrex [RW]	

▪ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5961

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 30

8134D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	26.36	27.81	[a] APX-Valaciclovir [TY]	[a] Shilova 500 [ZS]
					[a] Vaclovir [AF]	[a] Valaciclovir APOTEX [GX]
					[a] Valaciclovir generichealth [GQ]	[a] Valaciclovir RBX [RA]
					[a] Valaciclovir Sandoz [SZ]	[a] Valaciclovir SZ [HX]
					[a] Valacor 500 [CR]	[a] Zelitrex [RF]
		[B]2.43	28.79	27.81	[a] Valtrex [RW]	

▪ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

Authority required (STREAMLINED)

5960

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 10

8133C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*22.07	23.52	[a] APX-Valaciclovir [TY]	[a] Vaclovir [AF]
					[a] Valaciclovir APOTEX [GX]	[a] Valaciclovir Sandoz [SZ]
					[a] Zelitrex [RF]	
		[B]5.40	*27.47	23.52	[a] Valtrex [RW]	

▪ VALACICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5962

Herpes zoster

Clinical criteria:

- The treatment must be administered within 72 hours of the onset of the rash.

Authority required (STREAMLINED)

5968

Herpes zoster ophthalmicus

valaciclovir 500 mg tablet, 42

8064K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	31.52	31.60	[a] APX-Valaciclovir [TY]	[a] Vaclovir [AF]
					[a] Valaciclovir APOTEX [GX]	[a] Valaciclovir generichealth [GQ]
					[a] Valaciclovir RBX [RA]	[a] Valaciclovir Sandoz [SZ]
					[a] Valacor 500 [CR]	[a] Zelitrex [RF]
		[B]2.43	33.95	31.60	[a] Valtrex [RW]	

Protease inhibitors

▪ NIRMATRELVIR (&) RITONAVIR

Caution Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13759

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13821

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m^2)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

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Authority required (STREAMLINED)

15049

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m^2),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6

12996B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1115.31	31.60	Paxlovid [PF]

Antivirals for treatment of HCV infections

▪ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11344C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	17009.27	31.60	Maviret [VE]

▪ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11353M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	17009.27	31.60	Maviret [VE]

▪ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11354N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17009.27	31.60	Maviret [VE]

▪ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 100

12785X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*1062.81	31.60	Ibavyr [IX]

▪ SOFOSBUVIR + VELPATASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11147Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	12037.60	31.60	Epclusa [GI]

▪ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11658N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	12037.60	31.60	Vosevi [GI]

Antivirals for treatment of HIV infections, combinations

▪ TENOFOVIR DISOPROXIL + EMTRICITABINE

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

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

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

Restricted benefit

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

Clinical criteria:

- Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued: (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

11276L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	31.25	31.60	[a] CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR] [a] TENOFOVIR/EMTRICITABINE 300/200 ARX [XT]	[a] Tenofovir/Emtricitabine 300/200 APOTEX [TX]

tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30

12542D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	31.25	31.60	[a] Tenofovir/Emtricitabine Sandoz 301/200 [SZ]

tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30

11306C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	31.25	31.60	[a] Tenofovir EMT GH [GQ]

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

11296M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	31.25	31.60	[a] Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL]

VACCINES

BACTERIAL VACCINES

Tetanus vaccines

DIPHTHERIA + TETANUS VACCINE

Note For immunisation of adults and children aged greater than or equal to 8 years.

diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes

8783G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	74.82	31.60	ADT Booster [CS]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

CHLORAMBUCIL

chlorambucil 2 mg tablet, 25

1163F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	4	2	..	*136.71	31.60	Leukeran [AS]

CYCLOPHOSPHAMIDE

cyclophosphamide 50 mg tablet, 50

1266P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	157.09	31.60	Cyclonex [GH]

MELPHALAN

melphalan 2 mg tablet, 25

2547C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	65.41	31.60	Alkeran [AS]

Alkyl sulfonates

BUSULFAN

busulfan 2 mg tablet, 100

1128J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	79.49	31.60	Myleran [AS]

Nitrosoureas

CARMUSTINE

Note Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

Restricted benefit

Glioblastoma multiforme

Clinical criteria:

- The condition must be suspected or confirmed at the time of initial surgery.

carmustine 7.7 mg implant, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8898H	‡1	..	..	11150.92	31.60	Gliadel [EI]

Other alkylating agents

▪ TEMOZOLOMIDE

temozolomide 100 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8380C	1	5	..	77.65	31.60	[a] APO-Temozolomide [TX] [a] Temodal [MK]	[a] Temizole 100 [AL] [a] Temozolomide Juno [JX]

temozolomide 140 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9362R	1	5	..	101.98	31.60	[a] APO-Temozolomide [TX] [a] Temodal [MK]	[a] Temizole 140 [AL] [a] Temozolomide Juno [JX]

temozolomide 20 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8379B	1	5	..	28.44	29.89	[a] APO-Temozolomide [TX] [a] Temozolomide Juno [JX]	[a] Temizole 20 [AL]

temozolomide 250 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8381D	1	5	..	168.60	31.60	[a] APO-Temozolomide [TX] [a] Temozolomide Juno [JX]	[a] Temizole 250 [AL]

temozolomide 5 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8378Y	1	5	..	18.56	20.01	[a] APO-Temozolomide [TX] [a] Temozolomide Juno [JX]	[a] Temizole 5 [AL]

temozolomide 180 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2438H	1	5	..	121.02	31.60	[a] APO-Temozolomide [TX]	[a] Temozolomide Juno [JX]

▪ TEMOZOLOMIDE

Note Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

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

Restricted benefit

Glioblastoma multiforme

Treatment criteria:

- Patient must be undergoing concomitant radiotherapy.

temozolomide 100 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8821G	3	2	..	*210.66	31.60	[a] APO-Temozolomide [TX] [a] Temodal [MK]	[a] Temizole 100 [AL] [a] Temozolomide Juno [JX]

temozolomide 140 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9361Q	3	2	..	*287.31	31.60	[a] APO-Temozolomide [TX] [a] Temodal [MK]	[a] Temizole 140 [AL] [a] Temozolomide Juno [JX]

temozolomide 20 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8820F	3	2	..	*58.41	31.60	[a] APO-Temozolomide [TX] [a] Temozolomide Juno [JX]	[a] Temizole 20 [AL]

temozolomide 5 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8819E	3	2	..	*28.77	30.22	[a] APO-Temozolomide [TX] [a] Temozolomide Juno [JX]	[a] Temizole 5 [AL]

temozolomide 180 mg capsule, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10062N	3	2	..	*346.14	31.60	[a] APO-Temozolomide [TX]	[a] Temozolomide Juno [JX]

ANTIMETABOLITES

Folic acid analogues

▪ METHOTREXATE

methotrexate 5 mg/2 mL injection, 5 x 2 mL vials

2396D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	42.31	31.60	DBL Methotrexate [PF]

NP

methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

2395C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	40.88	31.60	DBL Methotrexate [PF]

NP

methotrexate 10 mg tablet, 15

2272N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	25.56	27.01	[a] ARX-Methotrexate [XT] [a] Methoblastin [PF]	[a] Chexate [OX]

NP

methotrexate 2.5 mg tablet, 30

1622J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.29	20.74	[a] ARX-Methotrexate [XT] [a] Methoblastin [PF]	[a] Chexate [OX]

NP

▪ METHOTREXATE

Restricted benefit

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

1623K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	53.78	31.60	[a] ARX-Methotrexate [XT] [a] Methoblastin [PF]	[a] Chexate [OX]

NP

▪ METHOTREXATE

Restricted benefit

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

methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

13882P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*68.31	31.60	DBL Methotrexate [PF]

Purine analogues

▪ FLUDARABINE

fludarabine phosphate 10 mg tablet, 20

9184J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	938.84	31.60	Fludara [GZ]

▪ MERCAPTOPURINE

mercaptopurine monohydrate 50 mg tablet, 25

1598D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*169.23	31.60	[a] MERCAPTOPURINE-LINK [LM]
		[B]7.44	*176.67	31.60	[a] Purinethol [AS]

mercaptopurine monohydrate 20 mg/mL oral liquid, 100 mL

10214N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	381.68	31.60	Allmercap [LM]

▪ TIOGUANINE

tioguanine 40 mg tablet, 25

1233X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	194.76	31.60	Lanvis [AS]

Pyrimidine analogues

▪ AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

azacitidine 200 mg tablet, 7

13623B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*13390.37	31.60	Onureg [CJ]

▪ AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Dose escalation therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail:

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

(c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.

All reports must be documented in the patient's medical records.

azacitidine 300 mg tablet, 7

13624C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	1	..	*20004.24	31.60	Onureg [CJ]

▪ AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Initial treatment

Clinical criteria:

- Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy, **AND**
- Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation, **AND**
- Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk, **AND**
- Patient must not have undergone a stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

A complete remission is defined as: bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count greater than 1.0 x 10^9/L and platelet count greater than or equal to 100 x 10^9/L.

A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than 1.0 x 10^9/L or platelet count less than 100 x 10^9/L.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

azacitidine 300 mg tablet, 7

13619T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*13372.33	31.60	Onureg [CJ]

▪ CAPECITABINE

capecitabine 500 mg tablet, 120

8362D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	49.65	31.60	[a] Capecitabine Alphapharm [AF]	[a] Capecitabine-DRLA [RZ]
					[a] Capecitabine Sandoz [SZ]	[a] Xelabine [AL]

▪ DECITABINE + CEDAZURIDINE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13258

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

decitabine 35 mg + cedazuridine 100 mg tablet, 5

13081L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4862.60	31.60	Inqovi 35/100 [OS]

▪ DECITABINE + CEDAZURIDINE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
PBS Authorities
GPO Box 9826
[Your capital city]

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

(a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) full blood examination report

decitabine 35 mg + cedazuridine 100 mg tablet, 5

13133F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4862.60	31.60	Inqovi 35/100 [OS]

▪ DECITABINE + CEDAZURIDINE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification.

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

(a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

(b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

(c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

(d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

(e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

(a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

(b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

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

(a) The patient's International Prognostic Scoring System (IPSS) score.

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

(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(b) full blood examination report; and

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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

(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and

(b) full blood examination report.

decitabine 35 mg + cedazuridine 100 mg tablet, 5

13087T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4862.60	31.60	Inqovi 35/100 [OS]

▪ DECITABINE + CEDAZURIDINE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

decitabine 35 mg + cedazuridine 100 mg tablet, 5

13107W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4862.60	31.60	Inqovi 35/100 [OS]

▪ TRIFLURIDINE + TIPIRACIL

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10309

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; OR
- Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority required (STREAMLINED)

8183

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

trifluridine 15 mg + tipiracil 6.14 mg tablet, 20

11507P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	2	..	*2284.02	31.60	Lonsurf 15/6.14 [SE]

trifluridine 20 mg + tipiracil 8.19 mg tablet, 20

11524M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*3934.07	31.60	Lonsurf 20/8.19 [SE]

▪ TRIFLURIDINE + TIPIRACIL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10252

Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority required (STREAMLINED)

10310

Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

trifluridine 15 mg + tipiracil 6.14 mg tablet, 20

12056M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	2	..	*2284.02	31.60	Lonsurf 15/6.14 [SE]

trifluridine 20 mg + tipiracil 8.19 mg tablet, 20

12033H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*3934.07	31.60	Lonsurf 20/8.19 [SE]

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

▪ VINORELBINE

Authority required

Advanced breast cancer

Clinical criteria:

- Patient must have failed standard prior therapy, which includes an anthracycline.

Authority required

Locally advanced or metastatic non-small cell lung cancer

vinorelbine 20 mg capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9009E	20	2	..	*1579.87	31.60	[a] Navelbine [FB]	[a] Velabine [XT]

vinorelbine 30 mg capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9010F	16	2	..	*1893.15	31.60	[a] Navelbine [FB]	[a] Velabine [XT]

Podophyllotoxin derivatives

▪ ETOPOSIDE

etoposide 100 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1389D	1	..	..	393.09	31.60	Vepesid [LM]

etoposide 50 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1396L	1	..	..	450.01	31.60	Vepesid [LM]

PROTEIN KINASE INHIBITORS

BCR-ABL tyrosine kinase inhibitors

▪ ASCIMINIB

Note Special Pricing Arrangements apply.

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

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

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

Authority required (STREAMLINED)

13923

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

asciminib 40 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13259W	1	5	..	6131.79	31.60	Scemblix [NV]

▪ ASCIMINIB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

13923

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

asciminib 20 mg tablet, 60

13268H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6175.10	31.60	Scemblix [NV]

▪ ASCIMINIB

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

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

Note Special Pricing Arrangements apply.

Note Tyrosine Kinase Inhibitors (TKI) are defined as either (i) imatinib, (ii) dasatinib, (iii) nilotinib

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

Note Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients without T315I mutation

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be in the blast phase, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have failed an adequate trial of at least two tyrosine kinase inhibitors; OR
- Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors; OR
- Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor.

Failure of an adequate trial of a tyrosine kinase inhibitor is defined as:

1. Lack of response defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or

(iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

asciminib 20 mg tablet, 60

13248G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6175.10	31.60	Scemblix [NV]

asciminib 40 mg tablet, 60

13264D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6131.79	31.60	Scemblix [NV]

▪ ASCIMINIB

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients with T315I mutation

Clinical criteria:

- The condition must not be in the blast phase, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority.

Failure of an adequate trial of a tyrosine kinase inhibitor is defined as:

1. Lack of response defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or

(iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and

(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

Note Tyrosine Kinase Inhibitors (TKI) are defined as either (i) imatinib, (ii) dasatinib, (iii) nilotinib, (iv) ponatinib

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing Treatment for patients with T315I mutation

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or

(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

asciminib 40 mg tablet, 60

13260X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	5	..	*30225.12	31.60	Scemblix [NV]

▪ DASATINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by

the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12522

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - third-line therapy

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

dasatinib 100 mg tablet, 30

12842X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

12888H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1193.94	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

12857Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

12866E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	2354.53	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

▪ DASATINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12565

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

dasatinib 100 mg tablet, 30

12889J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

12869H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1193.94	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

12843Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

12890K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	2354.53	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

▪ DASATINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for third-line treatment of CML.
1. Initial third-line treatment
Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.
2. Continuing treatment for third-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - third-line therapy

Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase; OR
- The condition must be in the blast phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting, **AND**
- Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised second-line treatment with nilotinib for this condition, **AND**

- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of nilotinib is defined as:

(i) Lack of response to second line nilotinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with nilotinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with nilotinib; OR

ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib and nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

dasatinib 100 mg tablet, 30

12902C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

12849G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1193.94	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

12865D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

12886F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	2354.53	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

▪ DASATINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for second-line treatment of CML.
1. Initial second-line treatment
A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment for second-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12530

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - second-line therapy

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

dasatinib 100 mg tablet, 30

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]

12859T						[a] Dasatinib SUN [RA] [a] Sprycel [BQ]	[a] DASATINIB-TEVA [TB] [a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12850H	1	5	..	1193.94	31.60	[a] Dasatinib ARX [XT] [a] Dasatinib SUN [RA] [a] Sprycel [BQ]	[a] Dasatinib Dr.Reddy's [RI] [a] DASATINIB-TEVA [TB] [a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12860W	1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT] [a] Dasatinib SUN [RA] [a] Sprycel [BQ]	[a] Dasatinib Dr.Reddy's [RI] [a] DASATINIB-TEVA [TB] [a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12903D	1	5	..	2354.53	31.60	[a] Dasatinib ARX [XT] [a] Dasatinib SUN [RA] [a] Sprycel [BQ]	[a] Dasatinib Dr.Reddy's [RI] [a] DASATINIB-TEVA [TB] [a] TE-DASATINIB [AF]

▪ DASATINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

dasatinib 100 mg tablet, 30

1416M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

1354G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1193.94	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

1381Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

1415L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	2354.53	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

▪ DASATINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

1. Initial second-line treatment
A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment for second-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - second-line therapy

Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase; OR
- The condition must be in the blast phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with nilotinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib or nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

dasatinib 100 mg tablet, 30

9342Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

2478K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1193.94	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

2482P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

2485T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	2354.53	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

▪ DASATINIB

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

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Note Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib, **AND**
- The condition must not have progressed.

Note Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

Note Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

dasatinib 100 mg tablet, 30

9343R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 20 mg tablet, 60

9125G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	1193.94	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 50 mg tablet, 60

9126H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	1924.28	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

dasatinib 70 mg tablet, 60

9127J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	2354.53	31.60	[a] Dasatinib ARX [XT]	[a] Dasatinib Dr.Reddy's [RI]
					[a] Dasatinib SUN [RA]	[a] DASATINIB-TEVA [TB]
					[a] Sprycel [BQ]	[a] TE-DASATINIB [AF]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10918P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9176Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10921T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9179D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10925B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9175X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR

- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10933K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9173T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10939R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9177B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10940T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9178C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10941W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9174W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10942X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9172R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9209

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11776T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11753N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9243

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11756R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11765F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9243

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11757T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11769K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9296

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11763D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11758W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9206

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11777W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11762C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9209

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11764E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11786H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9296

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11770L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11781C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

9206

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11779Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11785G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

9278

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

imatinib 100 mg capsule, 60

12710Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11784F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

9278

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

imatinib 400 mg capsule, 30

12711B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11788K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

imatinib 400 mg capsule, 30

12681K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

5444M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

imatinib 100 mg capsule, 60

12759M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

5443L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

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

Authority required (STREAMLINED)

13132

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 600 mg tablet, 30

12919Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

Authority required (STREAMLINED)

9209

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12923E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12927J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10915L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9113P	1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR

- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10916M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9114Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL

level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required (STREAMLINED)

12536

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11772N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11752M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required (STREAMLINED)

12536

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11782D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11775R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

13132

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to

400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 400 mg capsule, 30

12723P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11778X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

13132

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 100 mg capsule, 60

12722N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11787J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

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

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to

400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

12709X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9111M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

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

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

12754G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9112N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

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

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

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The condition must have not achieved a response with this drug at a dose of 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12926H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

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

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10917N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9124F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10920R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9115R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

[a] Imatinib-Teva [TB]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

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

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10924Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9123E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report

documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10935M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9116T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required (STREAMLINED)

9207

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

imatinib 400 mg capsule, 30

11771M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11789L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required (STREAMLINED)

9207

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

imatinib 100 mg capsule, 60

11783E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11780B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Authority required (STREAMLINED)

12542

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

Authority required (STREAMLINED)

12525

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

imatinib 400 mg capsule, 30

11870R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Imatinib-APOTEX [TX] [a] Imatinib GH [GQ]	[a] IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11878E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	289.69	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Authority required (STREAMLINED)

12542

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

Authority required (STREAMLINED)

12525

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

imatinib 100 mg capsule, 60

11875B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Imatinib-APOTEX [TX]	[a] IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11880G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	149.09	31.60	[a] Gilmat [CR] [a] IMATINIB RBX [RA] [a] Imatinib-Teva [TB]	[a] Glivec [NV] [a] Imatinib Sandoz [SZ]

▪ IMATINIB

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

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

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

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12911M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required (STREAMLINED)

12536

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR

- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12912N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

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

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required (STREAMLINED)

9207

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

imatinib 600 mg tablet, 30

12920B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12924F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

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

Authority required (STREAMLINED)

12542

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

Authority required (STREAMLINED)

12525

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

imatinib 600 mg tablet, 30

12928K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.09	31.60	Imatab [JU]

▪ IMATINIB

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

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

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12935T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	560.09	31.60	Imatab [JU]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

1. Initial second-line treatment

A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment for second-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12563

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - second-line therapy

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

nilotinib 200 mg capsule, 120

12858R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3780.40	31.60	Tasigna [NV]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12522

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - third-line therapy

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

nilotinib 200 mg capsule, 120

12867F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3780.40	31.60	Tasigna [NV]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12572

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

nilotinib 150 mg capsule, 120

12868G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2893.12	31.60	Tasigna [NV]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required (STREAMLINED)

12549

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Grandfather treatment for patients initiated with nilotinib 200 mg prior to 1 April 2012 as first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received PBS-subsidised treatment with nilotinib 200mg as a first-line therapy for this condition prior to 1 April 2012, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

nilotinib 200 mg capsule, 120

12885E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3780.40	31.60	Tasigna [NV]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - third-line therapy

Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting, **AND**
- Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of dasatinib is defined as:

(i) Lack of response to second-line dasatinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed dasatinib for the chronic phase of chronic myeloid leukaemia.Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib and dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

nilotinib 200 mg capsule, 120

12887G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3780.40	31.60	Tasigna [NV]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical

records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

nilotinib 150 mg capsule, 120

1309X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2893.12	31.60	Tasigna [NV]

▪ NILOTINIB

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for second-line treatment of CML.
1. Initial second-line treatment
A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment for second-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - second-line therapy

Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:

(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to.

50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib or dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

nilotinib 200 mg capsule, 120

9171Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3780.40	31.60	Tasigna [NV]

▪ PONATINIB

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.

Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or

3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and

3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or

4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

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

ponatinib 45 mg tablet, 30

11453T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6174.25	31.60	Iclusig [TK]

ponatinib 15 mg tablet, 60

11454W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	5490.78	31.60	Iclusig [TK]

▪ PONATINIB

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;

3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ponatinib 45 mg tablet, 30

10524X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6174.25	31.60	Iclusig [TK]

ponatinib 15 mg tablet, 60

10523W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	5490.78	31.60	Iclusig [TK]

▪ PONATINIB

Note 1. Continuing treatment.
For first continuing applications patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment.
2. Authority approval requirements.
Response criteria to treatment with ponatinib:
For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted within 18 months of the commencement of treatment with ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive first continuing treatment with this drug).
Thereafter, at no greater than 12 month intervals a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% must be sustained to receive subsequent continuing treatments with this drug.
3. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006).
4. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Note Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:

1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and

(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals.

The first continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or

(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals.

A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.

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

ponatinib 45 mg tablet, 30

10530F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6174.25	31.60	Iclusig [TK]

ponatinib 15 mg tablet, 60

10520Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5490.78	31.60	Iclusig [TK]

Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors

▪ AFATINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

afatinib 20 mg tablet, 28

11335N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

afatinib 30 mg tablet, 28

11341X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

afatinib 40 mg tablet, 28

11359W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

afatinib 50 mg tablet, 28

11329G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

▪ AFATINIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7613

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

afatinib 20 mg tablet, 28

11336P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

afatinib 30 mg tablet, 28

11348G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

afatinib 40 mg tablet, 28

11347F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

afatinib 50 mg tablet, 28

11342Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2750.40	31.60	Giotrif [BY]

▪ ERLOTINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

erlotinib 100 mg tablet, 30

10020J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	528.55	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

erlotinib 150 mg tablet, 30

10014C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	651.87	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

erlotinib 25 mg tablet, 30

10022L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	151.76	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

▪ ERLOTINIB

Authority required (STREAMLINED)

4600

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

Population criteria:

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

erlotinib 100 mg tablet, 30

10019H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	528.55	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

erlotinib 150 mg tablet, 30

10025P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	651.87	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

erlotinib 25 mg tablet, 30

10028T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	151.76	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

▪ ERLOTINIB

Authority required (STREAMLINED)

7446

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

erlotinib 100 mg tablet, 30

11260P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	528.55	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

erlotinib 150 mg tablet, 30

11259N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	651.87	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

erlotinib 25 mg tablet, 30

11263T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	151.76	31.60	[a] Erlotinib APOTEX [TX]	[a] Erlotinib Sandoz [SZ]

▪ GEFITINIB

Authority required (STREAMLINED)

7447

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

gefitinib 250 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11264W	1	3	..	536.84	31.60	Cipla Gefitinib [LR]

▪ GEFITINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

gefitinib 250 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8769M	1	3	..	536.84	31.60	Cipla Gefitinib [LR]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11620N	1	5	..	7582.10	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 40 mg tablet, 30

12233W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7582.10	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IB, II or IIIA non-small cell lung cancer

Treatment Phase: Adjuvant therapy

Population criteria:

- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.

Clinical criteria:

- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 40 mg tablet, 30

14162J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7582.10	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IB, II or IIIA non-small cell lung cancer

Treatment Phase: Adjuvant therapy

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with EGFR-TKI for non small cell lung cancer; OR
- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.

Clinical criteria:

- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 80 mg tablet, 30

14168Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7582.10	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- Patient must not have previously received this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 80 mg tablet, 30

11622Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7582.10	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

Population criteria:

- Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12232T	1	5	..	7582.10	31.60	Tagrisso [AP]

B-Raf serine-threonine kinase (BRAF) inhibitors

▪ DABRAFENIB

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

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

Note Special Pricing Arrangements apply.

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

dabrafenib 75 mg capsule, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11823G	1	3	..	7157.83	31.60	Tafinlar [NV]

dabrafenib 50 mg capsule, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11820D	1	3	..	4826.09	31.60	Tafinlar [NV]

▪ DABRAFENIB

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

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

Note Special Pricing Arrangements apply.

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

10157

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

dabrafenib 75 mg capsule, 120

2846T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	7157.83	31.60	Tafinlar [NV]

dabrafenib 50 mg capsule, 120

2963Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	4826.09	31.60	Tafinlar [NV]

▪ DABRAFENIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6013

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

dabrafenib 75 mg capsule, 120

10003L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7157.83	31.60	Tafinlar [NV]

dabrafenib 50 mg capsule, 120

2954L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4826.09	31.60	Tafinlar [NV]

▪ ENCORAFENIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12487

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have BRAF V600 variant positive metastatic colorectal cancer, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have received prior treatment with cetuximab for this condition; OR
- Patient must not have developed disease progression while receiving cetuximab for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have failed to respond to at least one other line of systemic therapy, **AND**
- Patient must have a WHO performance status of 2 or less.

encorafenib 75 mg capsule, 42

12814K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	3	..	*5303.46	31.60	Braftovi [FB]

▪ ENCORAFENIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12484

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

encorafenib 75 mg capsule, 42

12815L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*5303.46	31.60	Braftovi [FB]

▪ ENCORAFENIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

10271

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

encorafenib 50 mg capsule, 28

11937G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9	3	..	*7035.15	31.60	Braftovi [FB]

encorafenib 75 mg capsule, 42

11938H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	3	..	*7035.15	31.60	Braftovi [FB]

▪ ENCORAFENIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

6013

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

encorafenib 50 mg capsule, 28

11954E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9	5	..	*7035.15	31.60	Braftovi [FB]

encorafenib 75 mg capsule, 42

11949X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*7035.15	31.60	Braftovi [FB]

▪ VEMURAFENIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

10157

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

vemurafenib 240 mg tablet, 56

11076Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	3	..	*6691.51	31.60	Zelboraf [RO]

▪ VEMURAFENIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6013

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

vemurafenib 240 mg tablet, 56

11081F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*6691.51	31.60	Zelboraf [RO]

Anaplastic lymphoma kinase (ALK) inhibitors

▪ ALECTINIB

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

alectinib 150 mg capsule, 4 x 56

11226W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	6483.03	31.60	Alecensa [RO]

▪ BRIGATINIB

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

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment
Clinical criteria:
- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

brigatinib 180 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11984R	1	3	..	6815.68	31.60	Alunbrig [TK]

brigatinib 90 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11974F	1	3	..	6815.68	31.60	Alunbrig [TK]

brigatinib 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11980M	4	3	..	*6815.71	31.60	Alunbrig [TK]

▪ BRIGATINIB

Caution Careful monitoring of patients is required due to risk of developing pulmonary adverse events observed in patients within the first seven days of treatment with this drug. Patients must be instructed to report any new or worsening respiratory symptoms.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
Clinical criteria:
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

brigatinib 90 mg tablet [7] (&) brigatinib 180 mg tablet [21], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11976H	‡1	..	..	6815.68	31.60	Alunbrig [TK]

▪ CERITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
Clinical criteria:
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment
Clinical criteria:
- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ceritinib 150 mg capsule, 3 x 50

11056X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	6934.49	31.60	Zykadia [NV]

▪ CRIZOTINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

(a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

crizotinib 200 mg capsule, 60

10323H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	6934.49	31.60	Xalkori [PF]

crizotinib 250 mg capsule, 60

10322G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	6934.49	31.60	Xalkori [PF]

▪ CRIZOTINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

crizotinib 200 mg capsule, 60

11589Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	6934.49	31.60	Xalkori [PF]

crizotinib 250 mg capsule, 60

11594F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	6934.49	31.60	Xalkori [PF]

▪ LORLATINIB

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

lorlatinib 100 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12091J	1	3	..	7112.69	31.60	Lorviqua [PF]

lorlatinib 25 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12096P	1	3	..	7112.69	31.60	Lorviqua [PF]

Mitogen-activated protein kinase (MEK) inhibitors

▪ BINIMETINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10328

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition.

binimetinib 15 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11948W	2	3	..	*7396.83	31.60	Mektovi [FB]

▪ BINIMETINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

10306

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

binimetinib 15 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11961M	2	5	..	*7396.83	31.60	Mektovi [FB]

▪ COBIMETINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10033

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.

cobimetinib 20 mg tablet, 63

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11074W	1	3	..	7035.11	31.60	Cotellic [RO]

▪ COBIMETINIB

Note A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
6803
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

cobimetinib 20 mg tablet, 63

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11075X	1	5	..	7035.11	31.60	Cotellic [RO]

▪ TRAMETINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
10051
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment
Clinical criteria:

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition.

trametinib 500 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10403M	3	3	..	*5685.15	31.60	Mekinist [NV]

trametinib 2 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10382K	1	3	..	7526.00	31.60	Mekinist [NV]

▪ TRAMETINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Initial treatment
Clinical criteria:

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

Authority required
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

trametinib 500 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11821E	3	3	..	*5685.15	31.60	Mekinist [NV]

trametinib 2 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11819C	1	3	..	7526.00	31.60	Mekinist [NV]

▪ TRAMETINIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6752

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

trametinib 500 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10385N	3	5	..	*5685.15	31.60	Mekinist [NV]

trametinib 2 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10405P	1	5	..	7526.00	31.60	Mekinist [NV]

Cyclin-dependent kinase (CDK) inhibitors

▪ ABEMACICLIB

Note The Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. See the following literature publication for details:
Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Early breast cancer

Clinical criteria:

- The treatment must be adjuvant to surgical resection, **AND**
- The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), **AND**
- The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, **AND**
- The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab.

Treatment criteria:

- Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit.

Retain all pathology imaging and investigative test results in the patient's medical records.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

abemaciclib 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14105J	1	5	..	4250.45	31.60	Verzenio [LY]

abemaciclib 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14134X	1	5	..	4250.45	31.60	Verzenio [LY]

abemaciclib 50 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14116Y	1	5	..	4250.45	31.60	Verzenio [LY]

▪ ABEMACICLIB

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

abemaciclib 100 mg tablet, 56

11871T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4250.45	31.60	Verzenio [LY]

abemaciclib 150 mg tablet, 56

11868P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4250.45	31.60	Verzenio [LY]

abemaciclib 50 mg tablet, 56

11876C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4250.45	31.60	Verzenio [LY]

▪ PALBOCICLIB

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

palbociclib 100 mg tablet, 21

12819Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4250.45	31.60	Ibrance [PF]

palbociclib 125 mg tablet, 21

12822W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4250.45	31.60	Ibrance [PF]

palbociclib 75 mg tablet, 21

12818P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4250.45	31.60	Ibrance [PF]

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated with this drug.

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

ribociclib 200 mg tablet, 21

11385F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1847.51	31.60	Kisqali [NV]

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated with this drug.

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

ribociclib 200 mg tablet, 63

11386G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5254.62	31.60	Kisqali [NV]

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated with this drug.

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

ribociclib 200 mg tablet, 42

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11397W	1	5	..	3557.28	31.60	Kisqali [NV]

Mammalian target of rapamycin (mTOR) kinase inhibitors

▪ EVEROLIMUS

Authority required (STREAMLINED)

7431

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

everolimus 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11258M	1	5	..	458.19	31.60	Afinitor [NV]

everolimus 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11267B	1	5	..	1738.38	31.60	Afinitor [NV]

everolimus 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11254H	1	5	..	901.84	31.60	Afinitor [NV]

▪ EVEROLIMUS

Authority required

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

everolimus 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2818H	1	5	..	458.19	31.60	Afinitor [NV]

▪ EVEROLIMUS

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

Authority required

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC), **AND**
- Patient must be experiencing a minimum of two partial-onset seizures per week, **AND**
- The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

Population criteria:

- Patient must be at least 2 years of age.

everolimus 3 mg dispersible tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11599L	1	5	..	547.99	31.60	Afinitor [NV]

everolimus 5 mg dispersible tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11592D	1	5	..	901.63	31.60	Afinitor [NV]

everolimus 2 mg dispersible tablet, 30

11591C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	368.15	31.60	Afinitor [NV]

▪ EVEROLIMUS

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

Authority required (STREAMLINED)

8262

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

everolimus 3 mg dispersible tablet, 30

11608Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	547.99	31.60	Afinitor [NV]

everolimus 5 mg dispersible tablet, 30

11598K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	901.63	31.60	Afinitor [NV]

everolimus 2 mg dispersible tablet, 30

11607X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	368.15	31.60	Afinitor [NV]

▪ EVEROLIMUS

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

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

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

everolimus 10 mg tablet, 30

10135K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1738.38	31.60	Afinitor [NV]

everolimus 5 mg tablet, 30

10131F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	901.84	31.60	Afinitor [NV]

▪ EVEROLIMUS

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

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

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

11377T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1738.38	31.60	Afinitor [NV]

everolimus 5 mg tablet, 30

11362B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	901.84	31.60	Afinitor [NV]

▪ EVEROLIMUS

Authority required

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

Authority required

Metastatic (Stage IV) breast cancer

Clinical criteria:

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

Population criteria:

- Patient must not be pre-menopausal.

Note Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

2985D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1738.38	31.60	Afinitor [NV]

everolimus 5 mg tablet, 30

2819J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	901.84	31.60	Afinitor [NV]

▪ EVEROLIMUS

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

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

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

10132G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1738.38	31.60	Afinitor [NV]

everolimus 5 mg tablet, 30

10133H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	901.84	31.60	Afinitor [NV]

▪ EVEROLIMUS

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

Authority required (STREAMLINED)

7432

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

everolimus 10 mg tablet, 30

11262R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1738.38	31.60	Afinitor [NV]

everolimus 5 mg tablet, 30

11257L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	901.84	31.60	Afinitor [NV]

Human epidermal growth factor receptor 2 (HER2) tyrosine kinase inhibitors

▪ LAPATINIB

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

Authority required (STREAMLINED)

9360

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

lapatinib 250 mg tablet, 70

11251E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*2210.49	31.60	Tykerb [NV]

▪ LAPATINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
- Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; OR
- Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and

(ii) date of last treatment with a taxane and total number of cycles; or

(iii) dates of treatment with trastuzumab and pertuzumab; or

(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or

(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

All reports must be documented in the patient's medical records.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

lapatinib 250 mg tablet, 70

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9148L	2	2	..	*2210.49	31.60	Tykerb [NV]

Janus-associated kinase (JAK) inhibitors

▪ RUXOLITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13906

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

The severity of cGVHD is defined by the **National Institutes of Health** (NIH) criteria (Jagasia et al., 2015):

(a) Moderate cGVHD: at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1

(b) Severe cGVHD: at least 1 organ with a score of 3, or lung score of 2 or 3

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health** (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Authority required (STREAMLINED)

13867

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health** (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ruxolitinib 10 mg tablet, 56

13235N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4912.60	31.60	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

13241X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2510.53	31.60	Jakavi [NV]

▪ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

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

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

ruxolitinib 10 mg tablet, 56

10927D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10616R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*4912.61	31.60	Jakavi [NV]

ruxolitinib 15 mg tablet, 56

10615Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10617T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

▪ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and

(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and

b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and

c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ruxolitinib 10 mg tablet, 56

10913J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4912.60	31.60	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10614P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*4912.61	31.60	Jakavi [NV]

ruxolitinib 15 mg tablet, 56

10619X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4912.60	31.60	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10618W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4912.60	31.60	Jakavi [NV]

Vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitors

▪ AXITINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7433

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

axitinib 1 mg tablet, 28

10539Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1070.79	31.60	Inlyta [PF]

axitinib 5 mg tablet, 28

10556N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*4950.61	31.60	Inlyta [PF]

▪ AXITINIB

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

Note Special Pricing Arrangements apply.

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

axitinib 1 mg tablet, 28

10572K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*1070.79	31.60	Inlyta [PF]

axitinib 5 mg tablet, 28

10540R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4950.61	31.60	Inlyta [PF]

Bruton's tyrosine kinase (BTK) inhibitors

▪ ACALABRUTINIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication - as monotherapy

Clinical criteria:

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

acalabrutinib 100 mg tablet, 56

13792X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7414.57	31.60	CALQUENCE [AP]

▪ ACALABRUTINIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication - in combination with obinutuzumab

Clinical criteria:

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**

- The treatment must be initiated as a monotherapy for 1 Cycle with treatment in combination with obinutuzumab from Cycle 2 to 7 (refer to Product Information for timing of obinutuzumab and acalabrutinib doses) after which treatment must be monotherapy.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

acalabrutinib 100 mg tablet, 56

13810W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	6	..	7414.57	31.60	CALQUENCE [AP]

▪ ACALABRUTINIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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Note Pharmaceutical benefits that have the form acalabrutinib 100 mg capsule and acalabrutinib 100 mg tablet are equivalent for the purposes of substitution.

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

acalabrutinib 100 mg tablet, 56

13318Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7414.57	31.60	CALQUENCE [AP]

▪ ACALABRUTINIB

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

Note Special Pricing Arrangements apply.

Note For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

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

Note Pharmaceutical benefits that have the form acalabrutinib 100 mg capsule and acalabrutinib 100 mg tablet are equivalent for the purposes of substitution.

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

acalabrutinib 100 mg tablet, 56

13325H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7414.57	31.60	CALQUENCE [AP]

▪ IBRUTINIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

ibrutinib 140 mg capsule, 90

11213E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7954.15	31.60	Imbruvica [JC]

ibrutinib 280 mg tablet, 30

14074R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5356.97	31.60	Imbruvica [JC]

ibrutinib 420 mg tablet, 30

14085H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7954.15	31.60	Imbruvica [JC]

▪ IBRUTINIB

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

Note For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

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

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

Note Special Pricing Arrangements apply.

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

ibrutinib 140 mg capsule, 120

11419B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	10551.33	31.60	Imbruvica [JC]

ibrutinib 280 mg tablet, 30

14079B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5356.97	31.60	Imbruvica [JC]

ibrutinib 420 mg tablet, 30

14075T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

ibrutinib 560 mg tablet, 30

14086J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	10551.33	31.60	Imbruvica [JC]

▪ ZANUBRUTINIB

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Waldenstrom macroglobulinaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; OR
- Patient must be unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naive) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition.

Authority required

Waldenstrom macroglobulinaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

zanubrutinib 80 mg capsule, 120

13041J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	7932.56	31.60	Brukinsa [IE]

▪ ZANUBRUTINIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

zanubrutinib 80 mg capsule, 120

13616P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7932.56	31.60	Brukinsa [IE]

▪ ZANUBRUTINIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication

Clinical criteria:

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

zanubrutinib 80 mg capsule, 120

13628G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7932.56	31.60	Brukinsa [IE]

▪ ZANUBRUTINIB

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

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

Note Special Pricing Arrangements apply.

Note For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

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

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

zanubrutinib 80 mg capsule, 120

12891L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7932.56	31.60	Brukinsa [IE]

Phosphatidylinositol-3-kinase (Pi3K) inhibitors

▪ IDELALISIB

Note Special Pricing Arrangements apply.

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

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

Authority required (STREAMLINED)

12480

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

idelalisib 100 mg tablet, 60

12813J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5119.46	31.60	Zydelig [GI]

idelalisib 150 mg tablet, 60

12812H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5119.46	31.60	Zydelig [GI]

▪ IDELALISIB

Note Special Pricing Arrangements apply.

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

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Authority required

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records.

idelalisib 100 mg tablet, 60

11171Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5119.46	31.60	Zydelig [GI]

idelalisib 150 mg tablet, 60

11165P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5119.46	31.60	Zydelig [GI]

▪ IDELALISIB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR
- The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; OR
- Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

idelalisib 100 mg tablet, 60

11170X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5119.46	31.60	Zydelig [GI]

idelalisib 150 mg tablet, 60

11162L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5119.46	31.60	Zydelig [GI]

Other protein kinase inhibitors

▪ CABOZANTINIB

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

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7631

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

cabozantinib 20 mg tablet, 30

11374P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 40 mg tablet, 30

11368H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 60 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11367G	1	5	..	9472.60	31.60	Cabometyx [IS]

▪ CABOZANTINIB

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

Note Special Pricing Arrangements apply.

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

Authority required (STREAMLINED)

11880

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; OR
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.

cabozantinib 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11371L	1	2	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11369J	1	2	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 60 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11360X	1	2	..	9472.60	31.60	Cabometyx [IS]

▪ ENTRECTINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR

- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

entrectinib 200 mg capsule, 90

12092K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	7290.90	31.60	Rozlytrek [RO]

▪ GILTERITINIB

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

(a) Leukaemic cells in the CSF; or

(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or

(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or

(d) Extramedullary leukaemia.

gilteritinib 40 mg tablet, 84

13094E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	25145.60	31.60	Xospata [LL]

▪ GILTERITINIB

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

gilteritinib 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13093D	1	..	..	25145.60	31.60	Xospata [LL]

▪ LAROTRECTINIB

Note For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

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

Note Special Pricing Arrangements apply.

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

Authority required

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

Treatment criteria:

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing.

Clinical criteria:

- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

larotrectinib 100 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13043L	1	5	..	12537.60	31.60	Vitrakvi [BN]

larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13289K	1	5	..	4287.60	31.60	VITRAKVI [BN]

larotrectinib 25 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13027P	1	5	..	3256.35	31.60	Vitrakvi [BN]

▪ LAROTRECTINIB

Note For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Solid tumours (of any type) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion where treatment with this drug is/was initiated in a child

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

Population criteria:

- Patient must be/have been under 18 years of age (i.e. prior to their 18th birthday) at treatment initiation with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); OR
- The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date), **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

larotrectinib 100 mg capsule, 56

13031W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	12537.60	31.60	Vitrakvi [BN]

larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

13281B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4287.60	31.60	VITRAKVI [BN]

larotrectinib 25 mg capsule, 56

13029R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3256.35	31.60	Vitrakvi [BN]

▪ LENVATINIB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11168

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy.

Authority required (STREAMLINED)

8584

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

lenvatinib 4 mg capsule, 30

11638M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	2	..	*6162.60	31.60	Lenvima [EI]

▪ LENVATINIB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6604

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be refractory to radioactive iodine, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately repressed, **AND**
- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

Radioactive iodine refractory is defined as:

- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

Authority required (STREAMLINED)

6578

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

lenvatinib 4 mg capsule, 30

10952K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2126.51	31.60	Lenvima [EI]

lenvatinib 10 mg capsule, 30

10965D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4162.61	31.60	Lenvima [EI]

▪ LENVATINIB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13921

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

Authority required (STREAMLINED)

13972

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR

- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

lenvatinib 4 mg capsule, 30

13252L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4144.57	31.60	Lenvima [EI]

▪ LENVATINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14042

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received prior treatment with platinum-based chemotherapy, **AND**
- The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

Authority required (STREAMLINED)

14041

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

lenvatinib 4 mg capsule, 30

13290L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4144.57	31.60	Lenvima [EI]

lenvatinib 10 mg capsule, 30

13283D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4162.61	31.60	Lenvima [EI]

▪ LENVATINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13921

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR

- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

Authority required (STREAMLINED)

13972

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

lenvatinib 10 mg capsule, 30

13253M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4162.61	31.60	Lenvima [EI]

▪ NINTEDANIB

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

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

Note Special Pricing Arrangements apply.

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment,

(ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

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

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

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

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nintedanib 100 mg capsule, 60

11100F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1680.06	31.60	Ofev [BY]

nintedanib 150 mg capsule, 60

11106M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3238.32	31.60	Ofev [BY]

▪ NINTEDANIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Progressive fibrosing Interstitial lung disease

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed through a multidisciplinary team, **AND**
- The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication, **AND**
- The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5), **AND**
- Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted**,** adjusted for each of: (i) age, (ii) gender, (iii) height, **AND**
- The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both: (i) at least 30% predicted, (ii) no greater than 80% predicted, **AND**
- The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is), **AND**
- The condition must not be due to reversible causes (e.g. drug toxicity).

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Note Interstitial lung disease includes, but is not limited to:
(i) connective tissue associated interstitial lung disease;
(ii) chronic fibrosing hypersensitivity pneumonitis;
(iii) idiopathic non-specific interstitial pneumonia;
(iv) pulmonary sarcoidosis.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Progressive fibrosing Interstitial lung disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

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

nintedanib 100 mg capsule, 60

12967L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1680.06	31.60	Ofev [BY]

nintedanib 150 mg capsule, 60

12953R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3238.32	31.60	Ofev [BY]

▪ PAZOPANIB

Note Special Pricing Arrangements apply.

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required (STREAMLINED)

11939

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

pazopanib 200 mg tablet, 30

2232L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1137.85	31.60	Votrient [NV]

pazopanib 400 mg tablet, 30

2201W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2205.54	31.60	Votrient [NV]

▪ PAZOPANIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

9247

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:

adipocytic soft tissue sarcoma;
gastrointestinal stromal tumour (GIST);
rhabdomyosarcoma other than alveolar or pleomorphic;
chondrosarcoma;
osteosarcoma;
Ewings tumour/primitive neuroectodermal tumour;
dermofibromatosis sarcoma protuberans;
inflammatory myofibroblastic sarcoma;
malignant mesothelioma;
mixed mesodermal tumour of the uterus.

pazopanib 200 mg tablet, 90

10042M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3227.01	31.60	Votrient [NV]

pazopanib 400 mg tablet, 60

10041L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4248.48	31.60	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7458

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

pazopanib 200 mg tablet, 90

10047T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3227.01	31.60	Votrient [NV]

pazopanib 400 mg tablet, 60

10043N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4248.48	31.60	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7459

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

pazopanib 200 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10054E	1	5	..	1137.85	31.60	Votrient [NV]

pazopanib 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10052C	1	5	..	2205.54	31.60	Votrient [NV]

▪ PAZOPANIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required (STREAMLINED)

11937

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

pazopanib 200 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11252F	1	5	..	3227.01	31.60	Votrient [NV]

pazopanib 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11261Q	1	5	..	4248.48	31.60	Votrient [NV]

▪ PAZOPANIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.
Note Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Authority required (STREAMLINED)

11974

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

pazopanib 200 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2029T	1	2	..	3227.01	31.60	Votrient [NV]

pazopanib 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2030W	1	2	..	4248.48	31.60	Votrient [NV]

▪ RIPRETINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Special Pricing Arrangements apply.

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must not be resectable, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; OR
- The condition must have progressed despite each of: (i) treatment with a drug PBS-listed specifically listed for this PBS-indication, (ii) an intolerance/expected intolerance to all other drugs PBS-listed for this specific PBS-indication, **AND**
- Patient must have a WHO performance status of 2 or less.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug for the first time - retreatment/continuing treatment beyond the available repeat prescription is not permitted under this listing; see 'Continuing treatment' Treatment Phase listing to continue PBS-subsidised treatment in a patient without disease progression.

Note Currently PBS-listed drugs with the indication of: 'metastatic or unresectable malignant gastrointestinal stromal tumour' are: imatinib and sunitinib

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must not be resectable, **AND**
- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

ripretinib 50 mg tablet, 90

12764T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	16304.54	31.60	Qinlock [ZB]

▪ SORAFENIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60

10226F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4150.01	31.60	Nexavar [BN]

▪ SORAFENIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7487

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60

10242C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*4150.01	31.60	Nexavar [BN]

▪ SORAFENIB

Note Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.
Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11160

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy.

Authority required (STREAMLINED)

8617

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

sorafenib 200 mg tablet, 60

9380Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*4150.01	31.60	Nexavar [BN]

▪ SUNITINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

sunitinib 12.5 mg capsule, 28

10004M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	665.21	31.60	[a] Sunitinib MSN [LR] [a] Sutent [PF]	[a] Sunitinib Sandoz [SZ]

sunitinib 25 mg capsule, 28

2959R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1294.65	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 50 mg capsule, 28

2837H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2533.10	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 37.5 mg capsule, 28

10464R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1907.75	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

▪ SUNITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7471

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sunitinib 12.5 mg capsule, 28

10009T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	665.21	31.60	[a] Sunitinib MSN [LR] [a] Sutent [PF]	[a] Sunitinib Sandoz [SZ]

sunitinib 25 mg capsule, 28

2842N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1294.65	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 50 mg capsule, 28

10010W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	2533.10	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 37.5 mg capsule, 28

10473F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1907.75	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

▪ SUNITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required (STREAMLINED)

11875

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

sunitinib 12.5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9420T	1	3	..	665.21	31.60	[a] Sunitinib MSN [LR] [a] Sutent [PF]	[a] Sunitinib Sandoz [SZ]

sunitinib 25 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9421W	1	3	..	1294.65	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 50 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9422X	1	3	..	2533.10	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 37.5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10459L	1	3	..	1907.75	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

▪ SUNITINIB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesilate.

Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

sunitinib 12.5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9488J	1	1	..	665.21	31.60	[a] Sunitinib MSN [LR] [a] Sutent [PF]	[a] Sunitinib Sandoz [SZ]

sunitinib 25 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9489K	1	1	..	1294.65	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 50 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9490L	1	1	..	2533.10	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 37.5 mg capsule, 28

10503T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	1907.75	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

▪ SUNITINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

Authority required (STREAMLINED)

11878

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

sunitinib 12.5 mg capsule, 28

9417P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	665.21	31.60	[a] Sunitinib MSN [LR] [a] Sutent [PF]	[a] Sunitinib Sandoz [SZ]

sunitinib 25 mg capsule, 28

9418Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	1294.65	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 50 mg capsule, 28

9419R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	2533.10	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 37.5 mg capsule, 28

10504W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	1907.75	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

▪ SUNITINIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

13153

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

sunitinib 12.5 mg capsule, 28

11266Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	665.21	31.60	[a] Sunitinib MSN [LR] [a] Sutent [PF]	[a] Sunitinib Sandoz [SZ]

sunitinib 25 mg capsule, 28

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	1294.65	31.60	[a] ARX-Sunitinib [XT]	[a] Sunitinib MSN [LR]

11253G						[a] Sunitinib Sandoz [SZ]	[a] Sutent [PF]

sunitinib 50 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11250D	1	1	..	2533.10	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

sunitinib 37.5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11256K	1	1	..	1907.75	31.60	[a] ARX-Sunitinib [XT] [a] Sunitinib Sandoz [SZ]	[a] Sunitinib MSN [LR] [a] Sutent [PF]

▪ TEPOTINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13434

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of MET exon 14 skipping alterations in tumour material.

Authority required (STREAMLINED)

13441

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

tepotinib 225 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13171F	1	5	..	9104.80	31.60	Tepmetko [SG]

MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

CD38 (Clusters of Differentiation 38) inhibitors

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

Treatment criteria:

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12683M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	8	..	7172.88	31.60	Darzalex SC [JC]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12725R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7172.88	31.60	Darzalex SC [JC]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12755H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	7172.88	31.60	Darzalex SC [JC]

▪ DARATUMUMAB

Note The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Continuing treatment from week 25 onwards (administered once every four weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

daratumumab 1.8 g/15 mL injection, 15 mL vial

13199Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7172.88	31.60	Darzalex SC [JC]

▪ DARATUMUMAB

Note The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health

Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
PBS Authorities
GPO Box 9826
[Your capital city]

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Initial treatment from week 0 to week 24

Clinical criteria:

- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

daratumumab 1.8 g/15 mL injection, 15 mL vial

13202W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	15	..	7172.88	31.60	Darzalex SC [JC]

HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors

▪ TRASTUZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10212

Early HER2 positive breast cancer

Treatment Phase: 3 weekly treatment regimen

Clinical criteria:

- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10682F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1609.04	31.60	Herceptin SC [RO]

▪ TRASTUZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9353

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10798H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1609.04	31.60	Herceptin SC [RO]

▪ TRASTUZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9462

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10803N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1609.04	31.60	Herceptin SC [RO]

OTHER ANTINEOPLASTIC AGENTS

Histone deacetylase (HDAC) inhibitors

▪ VORINOSTAT

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

vorinostat 100 mg capsule, 120

11138F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4249.61	31.60	Zolinza [MK]

▪ VORINOSTAT

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

vorinostat 100 mg capsule, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11141J	1	1	..	4249.61	31.60	Zolinza [MK]

Hedgehog pathway inhibitors

▪ SONIDEGIB

Caution Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

sonidegib 200 mg capsule, 30

11304Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	7592.96	31.60	Odomzo [RA]

▪ VISMODEGIB

Caution Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

vismodegib 150 mg capsule, 28

11070P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	7097.60	31.60	Erivedge [RO]

Poly (ADP-ribose) polymerase (PARP) inhibitors

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 84

13079J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 56

13112D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 56

14094T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 84

14098B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg tablet, 84

14173Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg tablet, 84

14190W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg tablet, 56

14196E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg tablet, 56

14206Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg capsule, 56

13089X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg capsule, 84

13092C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**

- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

niraparib 100 mg capsule, 56

14088L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules

Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

niraparib 100 mg capsule, 84

14104H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

niraparib 100 mg tablet, 56

14172X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg tablet, 56

14179G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6637.44	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg tablet, 84

14207R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	9874.86	31.60	[a] Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form niraparib 100 mg capsule and niraparib 100 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

niraparib 100 mg tablet, 84

14212B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	9874.86	31.60	[a] Zejula [GK]

▪ OLAPARIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14760

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of subsequent-line maintenance therapy (BRCA1/2 gene mutation)

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial subsequent-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

olaparib 100 mg tablet, 56

11503K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

11539H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation)

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

olaparib 100 mg tablet, 56

12169L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

12161C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Definitions:

Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation)

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

olaparib 100 mg tablet, 56

11522K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

11528R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug.

olaparib 100 mg tablet, 56

12921C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

12913P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), **AND**
- Patient must have a WHO performance status of 2 or less.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time.

olaparib 100 mg tablet, 56

12932P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

12929L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation)

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

olaparib 100 mg tablet, 56

12170M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

12157W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

olaparib 100 mg tablet, 56

13782J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

13807Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Early breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug as adjuvant therapy for this condition, **AND**
- Patient must not have developed disease recurrence while receiving treatment with this drug for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit beyond a total of 52 weeks of treatment (including any non-PBS-subsidised supply), **AND**
- The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab.

olaparib 100 mg tablet, 56

14216F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	6	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

14215E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	6	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Early breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must have received neoadjuvant or adjuvant chemotherapy, **AND**
- The treatment must be adjuvant to surgical resection, **AND**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); OR
- Patient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; OR
- Patient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes, **AND**
- The treatment must not be a PBS-subsidised benefit beyond the following, whichever comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/(ii) has occurred, **AND**
- The treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy, **AND**
- The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab.

Retain all pathology imaging and investigative test results in the patient's medical records.

olaparib 100 mg tablet, 56

14181J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

14208T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6632.11	31.60	Lynparza [AP]

▪ OLAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)

Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

olaparib 100 mg tablet, 56

13783K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

13800H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

Other antineoplastic agents

▪ HYDROXYCARBAMIDE (HYDROXYUREA)

hydroxycarbamide (hydroxyurea) 500 mg capsule, 100

3093T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	47.78	31.60	[a] Hydrea [LM]	[a] HYDROXYCARBAMIDE MEDSURGE [DZ]

▪ VENETOCLAX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
- The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment under this restriction with this drug for this condition, whichever comes first.

venetoclax 100 mg tablet, 120

11639N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7404.47	31.60	Venclexta [VE]

▪ VENETOCLAX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Dose modification

Clinical criteria:

- The treatment must be for dose titration purposes.

venetoclax 10 mg tablet, 2

12999E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
7	..	..	*104.29	31.60	Venclexta [VE]

venetoclax 50 mg tablet, 7

11648C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	244.46	31.60	Venclexta [VE]

▪ VENETOCLAX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment prescription (treatment cycles 7 to 12 inclusive) of first-line therapy

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must cease upon disease progression; OR
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first.

venetoclax 100 mg tablet, 120

12199C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7404.47	31.60	Venclexta [VE]

▪ VENETOCLAX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 2 to 6 inclusive) of first-line therapy

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

venetoclax 100 mg tablet, 120

12205J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	7404.47	31.60	Venclexta [VE]

▪ VENETOCLAX

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Acute Myeloid Leukaemia

Clinical criteria:

- The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis), **AND**
- Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug, **AND**
- The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses), **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

venetoclax 100 mg tablet, 120

12803W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	7404.47	31.60	Venclexta [VE]

venetoclax 50 mg tablet, 7

12773G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*952.47	31.60	Venclexta [VE]

▪ VENETOCLAX

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Dose titration for relapsed/refractory disease

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

Treatment criteria:

- Patient must not be undergoing retreatment with this drug where any of: (i) prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; (ii) 24 months of PBS-subsidised treatment has been administered with this drug for this condition.

venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack

11630D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1706.50	31.60	Venclexta [VE]

▪ VENETOCLAX

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule)

Clinical criteria:

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).

venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack

12188L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1706.50	31.60	Venclexta [VE]

ENDOCRINE THERAPY

HORMONES AND RELATED AGENTS

Progestogens

MEDROXYPROGESTERONE

Restricted benefit

Advanced breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

2728N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	99.16	31.60	Provera [PF]

MEDROXYPROGESTERONE

Restricted benefit

Advanced breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

14038W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*188.43	31.60	Provera [PF]

MEDROXYPROGESTERONE

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

Restricted benefit

Endometrial cancer

medroxyprogesterone acetate 100 mg tablet, 100

2725K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	86.39	31.60	Provera [PF]

medroxyprogesterone acetate 200 mg tablet, 60

2316X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	96.64	31.60	Provera [PF]

medroxyprogesterone acetate 250 mg tablet, 60

2727M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	99.16	31.60	Provera [PF]

MEDROXYPROGESTERONE

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

Restricted benefit

Endometrial cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

medroxyprogesterone acetate 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14067J	2	2	..	*161.61	31.60	Provera [PF]

medroxyprogesterone acetate 200 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13881N	2	2	..	*183.13	31.60	Provera [PF]

medroxyprogesterone acetate 250 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13961T	2	2	..	*188.43	31.60	Provera [PF]

Gonadotropin releasing hormone analogues

▪ GOSERELIN

Restricted benefit

Carcinoma of the prostate

Clinical criteria:

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

goserelin 10.8 mg implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8093Y	1	1	..	714.56	31.60	Zoladex 10.8 Implant [AP]

▪ GOSERELIN

Restricted benefit

Carcinoma of the prostate

Clinical criteria:

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

Restricted benefit

Endometriosis

Clinical criteria:

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

Note Only 1 course of not more than 6 months' therapy will be authorised.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

Restricted benefit

Anticipated premature ovarian failure

Clinical criteria:

- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, **AND**
- Patient must not receive more than 6 months' of treatment for this condition in a lifetime.

Population criteria:

- Patient must be pre-menopausal.

goserelin 3.6 mg implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1454M	1	5	..	213.17	31.60	Zoladex Implant [AP]

▪ GOSERELIN (&) BICALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Carcinoma of the prostate

Clinical criteria:

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28], 1 pack

9065D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1043.25	31.60	ZolaCos CP 10.8/50(28) [AP]

goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84], 1 pack

9066E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	1322.92	31.60	ZolaCos CP 10.8/50(84) [AP]

goserelin 3.6 mg implant [1] (&) bicalutamide 50 mg tablet [28], 1 pack

9064C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	413.71	31.60	ZolaCos CP 3.6/50 [AP]

▪ LEUPRORELIN

Restricted benefit

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

leuprorelin acetate 22.5 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe

8876E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	714.56	31.60	Lucrin Depot 3 Month PDS [VE]

leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe

8877F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	940.53	31.60	Lucrin Depot 4 Month PDS [VE]

leuprorelin acetate 7.5 mg modified release injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber syringe

8875D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	271.00	31.60	Lucrin Depot 7.5mg PDS [VE]

leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8708H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	714.56	31.60	Eligard 3 month [MF]

leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8709J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	940.53	31.60	Eligard 4 month [MF]

leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8859G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1377.18	31.60	Eligard 6 month [MF]

leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8707G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	271.00	31.60	Eligard 1 month [MF]

leuprorelin acetate 45 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe

11943N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1377.18	31.60	Lucrin Depot 6-Month [VE]

▪ LEUPRORELIN

Restricted benefit

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe

11944P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	713.72	31.60	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ LEUPRORELIN

Restricted benefit

Central precocious puberty

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

Population criteria:

- Patient must be of an age that is prior to their 10th birthday if female; OR
- Patient must be of an age that is prior to their 11th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.

leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe

11960L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	713.72	31.60	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ LEUPRORELIN

Restricted benefit

Central precocious puberty

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

Population criteria:

- Patient must be of an age that is prior to their 10th birthday if female; OR
- Patient must be of an age that is prior to their 11th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.

Restricted benefit

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

13187C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1377.18	31.60	Eligard 6 month [MF]

▪ LEUPRORELIN (&) BICALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Carcinoma of the prostate

Clinical criteria:

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

10962Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	417.76	31.60	Bi ELIGARD CP [MF]

leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

10963B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	976.71	31.60	Bi ELIGARD CP [MF]

leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack

10969H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	1109.71	31.60	Bi ELIGARD CP [MF]

▪ TRIPTORELIN

Restricted benefit

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

9379P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	714.66	31.60	Diphereline [IS]

triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

9378N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	271.04	31.60	Diphereline [IS]

▪ TRIPTORELIN

Restricted benefit

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Restricted benefit

Central precocious puberty

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

Population criteria:

- Patient must be of an age that is prior to their 12th birthday if female; OR
- Patient must be of an age that is prior to their 13th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10th birthday if male.

Restricted benefit

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

5297T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1377.24	31.60	Diphereline [IS]

HORMONE ANTAGONISTS AND RELATED AGENTS

Anti-estrogens

▪ FULVESTRANT

Authority required (STREAMLINED)

11473

Locally advanced or metastatic breast cancer

Clinical criteria:

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable.

Population criteria:

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

fulvestrant 250 mg/5 mL injection, 2 x 5 mL syringes

12300J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	227.18	31.60	[a] FULVESTRANT ACCORD [OC] [a] Fulvestrant Sandoz [SZ]	[a] FULVESTRANT EVER PHARMA [IT]

▪ TAMOXIFEN

Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 30

1880Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	[B]5.52	*29.67	25.60	[a] Nolvadex-D [AP]

▪ TAMOXIFEN

Note For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 30

13960R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	[B]11.04	*45.87	31.60	[a] Nolvadex-D [AP]

▪ TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 60

2110C

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	24.15	25.60	[a] Genox 20 [AF] [a] Tamosin [OX]	[a] GenRx Tamoxifen [GX] [a] Tamoxifen Sandoz [SZ]

▪ TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

Note For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 60

13997Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*34.85	31.60	[a] Genox 20 [AF]	[a] GenRx Tamoxifen [GX]
					[a] Tamosin [OX]	[a] Tamoxifen Sandoz [SZ]

▪ TAMOXIFEN

Note A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Reduction of breast cancer risk

Clinical criteria:

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

tamoxifen 20 mg tablet, 30

10911G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18.80	20.25	[a] Genox 20 [AF]
		[B]2.76	21.56	20.25	[a] Nolvadex-D [AP]

▪ TAMOXIFEN

Note A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Reduction of breast cancer risk

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

tamoxifen 20 mg tablet, 30

13906X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*24.15	25.60	[a] Genox 20 [AF]
		[B]5.52	*29.67	25.60	[a] Nolvadex-D [AP]

▪ TOREMIFENE

toremifene 60 mg tablet, 30

8216K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	52.12	31.60	Fareston [OX]

▪ TOREMIFENE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

toremifene 60 mg tablet, 30

13859K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*90.79	31.60	Fareston [OX]

Anti-androgens

▪ APALUTAMIDE

Note Special Pricing Arrangements apply.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Authority required

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

apalutamide 60 mg tablet, 120

12992T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3715.90	31.60	Erlyand [JC]

▪ APALUTAMIDE

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

apalutamide 60 mg tablet, 120

13288J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3715.90	31.60	Erlyand [JC]

▪ BICALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5729

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

bicalutamide 50 mg tablet, 28

8094B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	52.54	31.60	[a] APO-Bicalutamide [TX] [a] Calutex [AS] [a] Cosudex [AP]	[a] Bicalox [ZS] [a] Cosamide 50 [AF]

▪ CYPROTERONE

cyproterone acetate 100 mg tablet, 50

8019C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	61.27	31.60	[a] ANTERONE 100 [RW] [a] Pharmacor Cyproterone 100 [CR]	[a] Cyproterone Sandoz [HX]
			[B]1.21	62.48	31.60	[a] Androcur-100 [GH]	

cyproterone acetate 50 mg tablet, 50

1270W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*74.87	31.60	[a] ANTERONE 50 [RW] [a] Pharmacor Cyproterone 50 [CR]	[a] Cyproterone Sandoz [HX]
			[B]1.96	*76.83	31.60	[a] Androcur [GH]	

▪ CYPROTERONE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

cyproterone acetate 100 mg tablet, 50

14022B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*109.09	31.60	[a] ANTERONE 100 [RW] [a] Pharmacor Cyproterone 100 [CR]	[a] Cyproterone Sandoz [HX]
			[B]2.42	*111.51	31.60	[a] Androcur-100 [GH]	

cyproterone acetate 50 mg tablet, 50

14023C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*137.39	31.60	[a] ANTERONE 50 [RW] [a] Pharmacor Cyproterone 50 [CR]	[a] Cyproterone Sandoz [HX]
			[B]4.12	*141.51	31.60	[a] Androcur [GH]	

▪ DAROLUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

darolutamide 300 mg tablet, 112

12684N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3538.24	31.60	Nubeqa [BN]

▪ DAROLUTAMIDE

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

darolutamide 300 mg tablet, 112

13769Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3538.24	31.60	Nubeqa [BN]

▪ ENZALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

enzalutamide 40 mg capsule, 112

10174L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3479.05	31.60	Xtandi [LL]

▪ ENZALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

enzalutamide 40 mg capsule, 112

13118K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3479.05	31.60	Xtandi [LL]

▪ ENZALUTAMIDE

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

enzalutamide 40 mg capsule, 112

13353T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3479.05	31.60	Xtandi [LL]

▪ FLUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5816

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

flutamide 250 mg tablet, 100

1417N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	175.70	31.60	Flutamin [AF]

Aromatase inhibitors

▪ ANASTROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

anastrozole 1 mg tablet, 30

8179L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	21.27	22.72	[a] Anastrozole GH [GQ] [a] APO-Anastrozole [TX]	[a] Anastrozole Sandoz [SZ] [a] Arianna 1 [AF]

▪ ANASTROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

anastrozole 1 mg tablet, 30

13858J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*29.09	30.54	[a] Anastrozole GH [GQ] [a] APO-Anastrozole [TX]	[a] Anastrozole Sandoz [SZ] [a] Arianna 1 [AF]

▪ EXEMESTANE

Restricted benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

- Patient must not be pre-menopausal.

exemestane 25 mg tablet, 30

10103R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	58.89	31.60	[a] APO-Exemestane [TX] [a] Exemestane Sandoz [SZ]	[a] Exemestane GH [GQ]
		[B]3.28	62.17	31.60	[a] Aromasin [PF]	

▪ EXEMESTANE

Restricted benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

- Patient must not be pre-menopausal.

exemestane 25 mg tablet, 30

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*104.33	31.60	[a] APO-Exemestane [TX]	[a] Exemestane GH [GQ]

14036R					[a] Exemestane Sandoz [SZ]
	[B]6.56	*110.89	31.60		[a] Aromasin [PF]

▪ EXEMESTANE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

exemestane 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8506Q NP	1	5	..	58.89	31.60	[a] APO-Exemestane [TX] [a] Exemestane Sandoz [SZ]	[a] Exemestane GH [GQ]
			[B]3.28	62.17	31.60	[a] Aromasin [PF]	

▪ EXEMESTANE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

exemestane 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13857H NP	2	5	..	*104.33	31.60	[a] APO-Exemestane [TX] [a] Exemestane Sandoz [SZ]	[a] Exemestane GH [GQ]
			[B]6.56	*110.89	31.60	[a] Aromasin [PF]	

▪ LETROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

letrozole 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8245Y NP	1	5	..	23.91	25.36	[a] ARX-LETROZOLE [XT] [a] Gynotril [ZS] [a] Letrozole GH [HQ] [a] Pharmacor Letrozole 2.5 [CR]	[a] Femolet [AF] [a] Letrozole APOTEX [GX] [a] Letrozole Sandoz [SZ]
			[B]2.64	26.55	25.36	[a] Femara 2.5 mg [NV]	

▪ LETROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Breast cancer
Clinical criteria:
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

letrozole 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13939P NP	2	5	..	*34.37	31.60	[a] ARX-LETROZOLE [XT]	[a] Femolet [AF]
						[a] Gynotril [ZS]	[a] Letrozole APOTEX [GX]
						[a] Letrozole GH [HQ]	[a] Letrozole Sandoz [SZ]
						[a] Pharmacor Letrozole 2.5 [CR]	
			[B]5.28	*39.65	31.60	[a] Femara 2.5 mg [NV]	

Other hormone antagonists and related agents

▪ ABIRATERONE

Caution The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Authority required
Castration resistant metastatic carcinoma of the prostate
Clinical criteria:
- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

abiraterone acetate 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11206T	1	2	..	3279.42	31.60	Zytiga [JC]

abiraterone acetate 250 mg tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2698B	1	2	..	3279.42	31.60	Zytiga [JC]

▪ ABIRATERONE (&) METHYLPREDNISOLONE

Caution The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Authority required
Castration resistant metastatic carcinoma of the prostate
Clinical criteria:
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR

- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack

13263C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	1295.50	31.60	Yonsa Mpred [RA]

▪ ABIRATERONE (&) METHYLPREDNISOLONE

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack

14078Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	1091.15	31.60	Yonsa Mpred [RA]

▪ DEGARELIX

Restricted benefit

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

2784M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	363.78	31.60	Firmagon 80mg [FP]

▪ DEGARELIX

Note No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

Restricted benefit

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack

2785N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	380.39	31.60	Firmagon 120mg [FP]

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

▪ INTERFERON BETA-1B

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7695

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

interferon beta-1b 8 million units (250 microgram) injection [15 vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack

8101J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	763.54	31.60	Betaferon [BN]

▪ PEGINTERFERON ALFA-2A

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11416W

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	543.04	31.60	Pegasys [XO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11037X

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	627.54	31.60	Pegasys [XO]

▪ PEGINTERFERON BETA-1A

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7695

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

10212L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	668.57	31.60	Plegridy [BD]

peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack

10218T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	668.57	31.60	Plegridy [BD]

▪ PEGINTERFERON BETA-1A

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

10220X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	668.57	31.60	Plegridy [BD]

Other immunostimulants

▪ GLATIRAMER ACETATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL syringes and pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL pen devices are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7695

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices

13110B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	668.57	31.60	[a] Copaxone [TB]

glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes

10416F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	629.06	31.60	[a] Copaxone [TB] [a] GLATIRAMER ACETATE-TEVA [EV]	[a] Glatira [JU]

▪ MYCOBACTERIUM BOVIS BCG DANISH STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials

12931N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡3	1	..	*1448.16	31.60	VesiCulture [LM]

▪ MYCOBACTERIUM BOVIS BCG TICE STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials

1131M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	459.47	31.60	OncoTICE [MK]

▪ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults

with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is

based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required (STREAMLINED)

14604

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

abatacept 125 mg/mL injection, 4 x 1 mL syringes

13726K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	946.96	31.60	Orencia [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

13727L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	946.96	31.60	Orencia ClickJect [BQ]

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are

included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

abatacept 125 mg/mL injection, 4 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1221G	1	5	..	946.96	31.60	Orencia [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11684Y	1	5	..	946.96	31.60	Orencia ClickJect [BQ]

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs

specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

abatacept 125 mg/mL injection, 4 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1220F	1	3	..	946.96	31.60	Orencia [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11693K	1	3	..	946.96	31.60	Orencia ClickJect [BQ]

▪ APREMILAST

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15326

Severe chronic plaque psoriasis

Clinical criteria:

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR
- Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

Population criteria:

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

apremilast 30 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12223H	1	5	..	654.18	31.60	Otezla [AN]

apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12218C	‡1	..	..	273.67	31.60	Otezla [AN]

▪ CLADRIBINE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10170

Relapsing remitting multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed by a neurologist, **AND**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**

- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

Authority required (STREAMLINED)

10171

Relapsing remitting multiple sclerosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

cladribine 10 mg tablet, 1

11603Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3803.99	31.60	Mavenclad [SG]

cladribine 10 mg tablet, 4

11604R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*29293.73	31.60	Mavenclad [SG]

cladribine 10 mg tablet, 6

11611D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	22010.94	31.60	Mavenclad [SG]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

8651H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	#287.57	31.60	[a] CellCept [RO]	[a] Pharmacor Mycophenolate [CR]

mycophenolate mofetil 500 mg tablet, 50

8650G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	5	..	*95.58	31.60	[a] ARX-MYCOPHENOLATE [XT] [a] Ceptolate [AF] [a] Mycophenolate APOTEX [GX] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] MycoCept [RF] [a] Mycophenolate GH [GQ] [a] Pharmacor Mycophenolate 500 [CR]

mycophenolate 180 mg enteric tablet, 120

2150E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	105.70	31.60	[a] Mycophenolic Acid ARX [XT]	[a] Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

2193K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	202.14	31.60	[a] Mycophenolic Acid ARX [XT] [a] Myfortic [NV]	[a] MYCOTEX [CR]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

14071N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡2	5	..	*#563.61	31.60	[a] CellCept [RO]	[a] Pharmacor Mycophenolate [CR]

mycophenolate mofetil 500 mg tablet, 50

14000W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	..	*180.87	31.60	[a] ARX-MYCOPHENOLATE [XT] [a] Ceptolate [AF] [a] Mycophenolate APOTEX [GX] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] MycoCept [RF] [a] Mycophenolate GH [GQ] [a] Pharmacor Mycophenolate 500 [CR]

mycophenolate 180 mg enteric tablet, 120

13856G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*202.17	31.60	[a] Mycophenolic Acid ARX [XT]	[a] Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

13938N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*395.83	31.60	[a] Mycophenolic Acid ARX [XT] [a] Myfortic [NV]	[a] MYCOTEX [CR]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

mycophenolate mofetil 250 mg capsule, 50

1836P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*95.67	31.60	[a] Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

8649F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	5	..	*95.67	31.60	[a] APO-Mycophenolate [TX] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] Pharmacor Mycophenolate 250 [CR]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 13884R and 14037T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

mycophenolate mofetil 250 mg capsule, 50

14037T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12	5	..	*181.11	31.60	[a] Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

13884R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	..	*181.11	31.60	[a] APO-Mycophenolate [TX] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] Pharmacor Mycophenolate 250 [CR]

Tumor necrosis factor alpha (TNF-alpha) inhibitors

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10399H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12379M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing

treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10400J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12411F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (recommencement of treatment) restriction to complete 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12449F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*1346.05	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12395J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*1346.05	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12436M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*711.71	31.60	Amgevita [XT]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first

application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority required

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10412B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12413H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the

baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority required

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10420K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12341M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is

increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11631

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12352D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13225C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have

completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11524

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum of 24 weeks treatment will be authorised under this restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12353E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13230H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11604

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12365T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13209F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to

respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11524

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum of 24 weeks treatment will be authorised under this restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12367X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13220T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority required

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9191R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12389C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Humira [VE]
					[a] Yuflyma [EW]	

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11604

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12401Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13223Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the

same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority required

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12410E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Humira [VE]
					[a] Yuflyma [EW]	

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11523

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12415K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13214L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and

infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12420Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13224B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12434K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13218Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11631

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12437N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13219R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years)

[further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11523

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12438P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13216N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather'

treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11529

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12330Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1354.49	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13221W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1108.87	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered

complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and

Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11579

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12351C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*711.71	31.60	Amgevita [XT]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-

subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12423W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	707.17	31.60	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12354F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*711.71	31.60	[a] Amgevita [XT]

▪ ADALIMUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (recommencement of treatment) restriction to complete 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12385W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	2	..	*1354.49	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12383R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	2	..	*1108.87	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12448E

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2		5	..	*1346.05	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12408C

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2		5	..	*1346.05	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their

treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11579

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12325Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13213K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11579

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12334E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13211H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a

treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the

PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11635

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

11606

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]

12366W		[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13217P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of

treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

11635

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

11606

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12403T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13215M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority required

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12424X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	707.17	31.60	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12440R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*711.71	31.60	[a] Amgevita [XT]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of

the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**

- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12419P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12372E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12326R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13222X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14683

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

14701

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12327T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13208E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14683

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

14701

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12328W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13226D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12329X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13227E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24

months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5283C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12399N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

5284D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12425Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Humira [VE]
					[a] Yuflyma [EW]	

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14567

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

13686H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13703F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been

initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14567

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

13721E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13732R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12369B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1354.49	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12414J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1108.87	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that

course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
Prescribing the 40 mg presentation:
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
Prescribing the 80 mg presentation:
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12360M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12393G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**

Prescribing the 80 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Requests for quantities/repeats insufficient to complete 16 weeks:
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12426B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12409D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12450G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12524E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10960W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12391E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR]	[a] Humira [VE]
					[a] Yuflyma [EW]	

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10961X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12358K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a

PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted

no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12337H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	707.17	31.60	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12357J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*711.71	31.60	[a] Amgevita [XT]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9078T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12361N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing

spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9104E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12363Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR]	[a] Humira [VE]
					[a] Yuflyma [EW]	

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab,

etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9102C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12375H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a

treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9100Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12390D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to

Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9034L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12398M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle

and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8964T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12405X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8741C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12430F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have

completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

8966X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12446C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to

commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Requests for quantities/repeats insufficient to complete 16 weeks:

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10413C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12388B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Requests for quantities/repeats insufficient to complete 16 weeks:

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of

this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10419J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12416L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease

may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
Prescribing the 40 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
Prescribing the 80 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Requests for quantities/repeats insufficient to complete 16 weeks:
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12338J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12455M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further

details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
Prescribing the 40 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
Prescribing the 80 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Requests for quantities/repeats insufficient to complete 16 weeks:
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12373F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12432H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*1659.06	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a

PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted

no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note No increase in the maximum number of repeats may be authorised.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
Prescribing the 40 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Prescribing the 80 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance

necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**

- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12374G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12339K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12356H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12454L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*1659.06	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological

treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9428F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12377K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9427E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12422T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease

may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
Prescribing the 40 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
Prescribing the 80 mg presentation:
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Requests for quantities/repeats insufficient to complete 16 weeks:
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer

than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12407B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	707.17	31.60	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12332C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*711.71	31.60	[a] Amgevita [XT]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12340L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12381P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*1659.06	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
Treatment cycle:
A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However,

the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12345R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

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Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*1659.06	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept

and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is

important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12364R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12447D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	677.26	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12394H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	677.26	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12428D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different

pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR

- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12451H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12453K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2014.86	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat

prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13691N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of

application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

13692P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13704G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

13722F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

13744J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP)

levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by

a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

13754X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13763J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	677.26	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13764K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	558.66	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However,

prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5281Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an

alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

5282B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the

baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12331B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8963R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at

any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
Prescribing the 40 mg presentation:
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
Prescribing the 80 mg presentation:
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12380N	3	..	..	*2014.86	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12397L	1	2	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12386X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

8965W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the

time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR

- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12387Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9188N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12402R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9190Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12362P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12376J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12378L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed

between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12400P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine,

'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot

be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12429E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
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Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12442W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8737W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9033K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID

therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional

Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9077R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction

necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated

according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9099X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to

Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9101B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment

cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9103D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10944B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12333D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**

- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10955N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12370C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.52	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the

maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

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Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after

the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12359L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12382Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**

- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12347W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*1659.06	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12412G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the

second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

Prescribing the 40 mg presentation:

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For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12371D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	707.17	31.60	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12350B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*711.71	31.60	[a] Amgevita [XT]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12342N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	558.66	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12421R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	677.26	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9425C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and

scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribing the 80 mg presentation:

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9426D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	4	..	681.48	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ CERTOLIZUMAB PEGOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10892G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11321W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10897M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11318Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more

than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active

joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10896L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11326D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.
A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.
Treatment cycles:
A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.
Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.
Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.
Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12005W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12028C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding

biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12040Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12013G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be

subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of

more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

13735X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

13701D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10137M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11320T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level

respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10238W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11324B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to

provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

3425G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11325C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1027.15	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab

course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10905Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3018.99	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11322X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3018.99	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12063X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3018.99	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12027B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3018.99	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing

spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10904X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3018.99	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11319R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3018.99	31.60	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response

following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10909E	3	..	..	*3018.99	31.60	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11323Y	3	..	..	*3018.99	31.60	Cimzia [UC]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response

following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

9156

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11202N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11216H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11197H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11204Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline

measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3448L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11201M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11196G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be

determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11218K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11211C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious

infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14629

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13708L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13707K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy

before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

3450N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

3449M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14683

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

14701

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11215G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11217J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

8887

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

8955

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11221N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11225T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline

PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.
Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified from week 12; and
(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14509

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority required (STREAMLINED)

14508

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

13693Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment

under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8638P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8779C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9456Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9086F	1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9460X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9090K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11207W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24

months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a

minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3445H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological

therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9036N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of

treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11198J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11208X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Caution Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.
Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to

ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.
Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified from week 12; and
(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14509

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority required (STREAMLINED)

14508

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13697X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	846.09	31.60	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13733T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	846.09	31.60	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated

according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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etanercept 50 mg/mL injection, 4 x 1 mL pen devices

3447K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	846.09	31.60	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

3446J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	846.09	31.60	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9458T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9088H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where

they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11223Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9429G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11222P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11224R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9462B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9431J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13687J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13698Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13774Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13751R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8637N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis',

further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9459W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9089J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.
Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus

psoriasis affecting the face, hand and foot.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a

PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.
Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified from week 12; and
(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**

- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

Treatment criteria:

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

Clinical criteria:

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.
In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:
(i) there is an absence of an adequate response to that treatment; or
(ii) there was an intolerance to that treatment; or
(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.
The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Authority required

Severe chronic plaque psoriasis
Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

Treatment criteria:

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

Clinical criteria:

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

1954W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8778B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they

are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or

recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9035M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot

change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional

Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9455P	1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9085E	1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in

biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9457R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9087G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ ETANERCEPT

Caution Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.
Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified from week 12; and
(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

Treatment criteria:

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

Clinical criteria:

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**

- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

Treatment criteria:

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

Clinical criteria:

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

1964J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

1963H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in

biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week

for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

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Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9037P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*846.11	31.60	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9461Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9091L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	846.09	31.60	[a] Brenzys [RF]	[a] Enbrel [PF]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice.

Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

golimumab 100 mg/mL injection, 1 mL pen device

11502J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1124.06	31.60	Simponi [JC]

▪ GOLIMUMAB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11521J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11516D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab

course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required (STREAMLINED)

14604

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

13706J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

13699B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant

restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11373N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3432P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the

full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11375Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3428K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11376R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3436W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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golimumab 100 mg/mL injection, 1 mL pen device

11381B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1124.06	31.60	Simponi [JC]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

golimumab 100 mg/mL injection, 1 mL pen device

11382C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*3295.89	31.60	Simponi [JC]

▪ GOLIMUMAB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there

has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**

- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Clinical criteria:

- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks duration under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11538G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11560K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to

Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a

minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11365E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3430M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last

prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11372M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3426H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1161.96	31.60	Simponi [JC]

▪ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must

submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11361Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1161.96	31.60	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3434R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1161.96	31.60	Simponi [JC]

▪ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application

following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

Population criteria:

- Patient must be at least 18 years of age.

infliximab 120 mg/mL injection, 1 mL syringe

12555T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	384.18	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12566J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	293.41	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing

treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

infliximab 120 mg/mL injection, 1 mL syringe

13078H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13056E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

infliximab 120 mg/mL injection, 1 mL syringe

13058G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13070X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

infliximab 120 mg/mL injection, 1 mL syringe

13074D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13061K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment

phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR

- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

infliximab 120 mg/mL injection, 1 mL syringe

13065P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13075E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

Population criteria:

- Patient must be at least 18 years of age.

infliximab 120 mg/mL injection, 1 mL syringe

12550M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12584H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide

more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note No increase in the maximum quantity or number of units may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

Population criteria:

- Patient must be at least 18 years of age.

infliximab 120 mg/mL injection, 1 mL syringe

12597B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12567K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 120 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12552P	2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12587L	2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be

subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of

more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

infliximab 120 mg/mL injection, 1 mL syringe

12553Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12554R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

infliximab 120 mg/mL injection, 1 mL syringe

12586K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12560C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the

restriction, it includes such benefits for PBS administrative purposes.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
Treatment cycle:
A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

12585J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12551N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional

Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

12561D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12575W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1

application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional

Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

12576X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

12577Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant

restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

infliximab 120 mg/mL injection, 1 mL syringe

13047Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13054C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

All measurements provided must be no more than 1 month old at the time of application.

infliximab 120 mg/mL injection, 1 mL syringe

13069W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13048R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements

will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

13057F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13049T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the condition is affecting the whole body, an adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle. State the qualifying PASI score in the authority application.

Where the condition is affecting the face/hand/foot, an adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) A reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or, sustained at this level, as compared to the baseline values. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; or

(ii) A reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle. State the qualifying numerical percentage figure in the authority application for each affected area.

All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.

infliximab 120 mg/mL injection, 1 mL syringe

13050W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13076F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks

following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

13072B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13055D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The most recent fistula assessment must be no more than 1 month old at the time of application.

infliximab 120 mg/mL injection, 1 mL syringe

13073C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13060J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**

- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

13067R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13062L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for

infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing

treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL syringe

13066Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*759.91	31.60	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL pen device

13077G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*578.35	31.60	Remsima SC [EW]

Interleukin inhibitors

▪ BIMEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than

5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

13644D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	3422.60	31.60	Bimzelx [UC]

▪ BIMEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Grandfathered patient - Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

- Patient must have a documented severe chronic plaque psoriasis where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023, **AND**
- Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- Patient must have a documented Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and

(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Note A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

- Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023, **AND**
- Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and

(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Note A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Grandfathered patient - Face, hand, foot or Whole body - Balance of Supply

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

13652M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3422.60	31.60	Bimzelx [UC]

▪ GUSELKUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in

biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

guselkumab 100 mg/mL injection, 1 x 1 mL syringe

12590P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3615.49	31.60	Tremfya [JC]

guselkumab 100 mg/mL injection, 1 x 1 mL pen device

12568L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3615.49	31.60	Tremfya [JC]

▪ GUSELKUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of

at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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guselkumab 100 mg/mL injection, 1 x 1 mL syringe

11614G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3615.49	31.60	Tremfya [JC]

▪ IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a

biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

12209N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3259.60	31.60	Taltz [LY]

▪ IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a

treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the

PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11033Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3259.60	31.60	Taltz [LY]

▪ IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised

adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

12217B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3259.60	31.60	Taltz [LY]

▪ IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological

medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on

the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11623R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3259.60	31.60	Taltz [LY]

▪ IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11032P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	3259.60	31.60	Taltz [LY]

▪ RISANKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

risankizumab 150 mg/mL injection, 1 mL pen device

14142H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	5401.89	31.60	Skyrizi [VE]

▪ RISANKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24

weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

risankizumab 150 mg/mL injection, 1 mL pen device

14111Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	5401.89	31.60	Skyrizi [VE]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is

prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

secukinumab 150 mg/mL injection, 1 mL pen device

10893H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	711.03	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14164L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10494H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

secukinumab 150 mg/mL injection, 1 mL pen device

10898N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	711.03	31.60	Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10901R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the

indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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secukinumab 150 mg/mL injection, 1 mL pen device

10906B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	711.03	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment

in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.
Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

secukinumab 150 mg/mL injection, 1 mL pen device

12297F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	711.03	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks

of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

secukinumab 150 mg/mL injection, 1 mL pen device

12307R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	711.03	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2024, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics

(v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14146M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of

moderate to severe hidradenitis suppurativa.
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR

- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14161H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

This restriction is intended for induction dosing only.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14154Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*5428.87	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological

therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

secukinumab 150 mg/mL injection, 1 mL pen device

10895K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	711.03	31.60	Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10899P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR

- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

secukinumab 150 mg/mL injection, 1 mL pen device

10890E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*2784.91	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in

therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

secukinumab 150 mg/mL injection, 1 mL pen device

12321L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*3454.02	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10425Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response

following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date

of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

secukinumab 150 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10900Q	4	..	..	*2784.91	31.60	Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10894J	4	..	..	*5428.87	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week

for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10910F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*5428.87	31.60	Cosentyx [NV]

▪ TILDRAKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tildrakizumab 100 mg/mL injection, 1 mL syringe

11613F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3117.15	31.60	Ilumya [RA]

▪ TILDRAKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tildrakizumab 100 mg/mL injection, 1 mL syringe

11616J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3117.15	31.60	Ilumya [RA]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(7) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

14150

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be 30kg or over, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11742B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11720W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years.
This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.
Alternative biological medicine refers to adalimumab and etanercept.
Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12761P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12762Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.
This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.
Alternative biological medicine refers to adalimumab and etanercept.
Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12767Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12768B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023

and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(7) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14104

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be under 30kg, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

13306H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

13301C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active giant cell arteritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11722Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	6	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11721X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	6	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11750K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11730J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active giant cell arteritis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

Clinical criteria:

- Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, **AND**
- Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR
- Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR
- Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, **AND**
- Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, **AND**
- Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR
- Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; OR
- Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis, **AND**
- The treatment must be in combination with a tapering course of corticosteroids, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

Population criteria:

- Patient must be aged 50 years or older.

Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include:

(a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and

(b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11744D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11743C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe

active systemic juvenile idiopathic arthritis (sJIA).
Treatment cycles:
From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.
Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
Prescribing under the correct 'Treatment Phase' listing for the authority application.
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.
(2) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.
(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.
(4) Baseline measurements to determine response.
Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any weight being administered a subcutaneous form of this biological medicine

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12094M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12102Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

13720D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

13685G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.
Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
Prescribing under the correct 'Treatment Phase' listing for the authority application.
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.
(2) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.
(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.
(4) Baseline measurements to determine response.
Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

14088

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing at least 30 kg

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The following reports must be documented in the patient's medical records where appropriate:

(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and

(b) baseline and current pathology reports detailing platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12084B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12099T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented

in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

14084

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing less than 30 kg

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12090H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12086D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.
The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12792G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12806B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11567T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10954M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11725D	1	3	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11741Y	1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".
Treatment cycles:
From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle

where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment Phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(7) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11734N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11748H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing at least 30 kg)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(b) details of prior treatment including dose and duration of treatment; and

(c) the pathology reports detailing CRP and platelet count where appropriate.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12083Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12095N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing less than 30 kg)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12085C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12105D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11565Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10951J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

▪ USTEKINUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed

a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment (Whole body, or, face/hand/foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12662K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	3944.61	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.
Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing

from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted supply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (Whole body) - treatment covering week 28 and onwards

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12664M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3944.61	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

ustekinumab 90 mg/mL injection, 1 mL syringe

13261Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3971.68	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The most recent fistula assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have had prior to commencing non-PBS-subsidised treatment: (1) confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; (2) an externally draining enterocutaneous or rectovaginal fistula, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition if received at least 12 weeks of initial non-PBS-subsidised therapy.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed baseline Fistula Assessment Form prior to initiating treatment including the date of assessment;

(ii) the completed current Fistula Assessment Form including the date of assessment demonstrating the patient's adequate response to treatment if the patient has received at least 12 weeks of treatment.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. No repeats will be authorised for patients transitioning from non-PBS-subsidised to PBS-subsidised treatment who have only received the first infusion of ustekinumab.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

ustekinumab 90 mg/mL injection, 1 mL syringe

13789R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3971.68	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10767Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3944.61	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and

wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

9305R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	3944.61	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR

- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

ustekinumab 90 mg/mL injection, 1 mL syringe

13273N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	3971.68	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ustekinumab 90 mg/mL injection, 1 mL syringe

13805N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	3971.68	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10774C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3944.61	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment

cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.
Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Ustekinumab only:
To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note The 28-weeks of treatment provided by this listing is intended to cover doses occurring at week 0, week 4 and week 16. Based on body weight, request an amount of biological medicine sufficient to cover a dose occurring at these timepoints. The original prescription is intended to cover a dose at week 0 and the 2 repeat prescriptions available are intended to cover doses at week 4 and week 16.
The dose due at week 28 is obtained with the first prescription obtained under the 'Continuing treatment' phase. Remind the patient to return for clinical review at approximately week 24 of treatment to enable ample time to obtain the authority application enabling dosing from week 28 and onwards.
Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified; and
(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR

- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 3 doses available under any of the initial treatment phases.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12669T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3944.61	31.60	Stelara [JC]

▪ USTEKINUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months.

Note Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

11178H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*7780.77	31.60	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence

such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

9304Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3944.61	31.60	Stelara [JC]

Calcineurin inhibitors

▪ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

ciclosporin 10 mg capsule, 60

8657P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*93.47	31.60	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

8660T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*219.47	31.60	[a] APO-Ciclosporin [TX] [a] Neoral 100 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 25 mg capsule, 30

8658Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*60.87	31.60	[a] APO-Ciclosporin [TX] [a] Neoral 25 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 50 mg capsule, 30

8659R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*112.11	31.60	[a] APO-Ciclosporin [TX] [a] Neoral 50 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 100 mg/mL oral liquid, 50 mL

8661W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*700.05	31.60	Neoral [NV]

▪ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

ciclosporin 10 mg capsule, 60

13999T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	3	..	*176.47	31.60	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

13911E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	3	..	*430.47	31.60	[a] APO-Ciclosporin [TX] [a] Neoral 100 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 25 mg capsule, 30

13883Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	3	..	*108.27	31.60	[a] APO-Ciclosporin [TX] [a] Neoral 25 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 50 mg capsule, 30

13910D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	3	..	*215.59	31.60	[a] APO-Ciclosporin [TX] [a] Neoral 50 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 100 mg/mL oral liquid, 50 mL

14001X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	3	..	*1391.63	31.60	Neoral [NV]

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

tacrolimus 5 mg modified release capsule, 30

5451X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	430.86	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 500 microgram capsule, 100

8646C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	81.35	31.60	[a] Pacrolim [AF] [a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]	[a] Pharmacor Tacrolimus 0.5 [CR] [a] Tacrograf [RW]

tacrolimus 500 microgram modified release capsule, 30

5299X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	53.80	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 1 mg capsule, 100

8647D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	151.04	31.60	[a] Pacrolim [AF] [a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]	[a] Pharmacor Tacrolimus 1 [CR] [a] Tacrograf [RW]

tacrolimus 1 mg modified release capsule, 60

5300Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	94.94	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 5 mg capsule, 50

8648E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	364.73	31.60	[a] Pharmacor Tacrolimus 5 [CR] [a] Tacrograf [RW]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10870D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	119.19	31.60	Tacrolimus Sandoz [SZ]

tacrolimus 2 mg capsule, 100

10871E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	333.38	31.60	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

11914C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	380.00	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

tacrolimus 5 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14039X	2	3	..	*853.27	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 500 microgram capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13908B	2	3	..	*151.03	31.60	[a] Pacrolim [AF] [a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]	[a] Pharmacor Tacrolimus 0.5 [CR] [a] Tacrograf [RW]

tacrolimus 500 microgram modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13907Y	2	3	..	*94.15	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 1 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14070M	2	3	..	*293.61	31.60	[a] Pacrolim [AF] [a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]	[a] Pharmacor Tacrolimus 1 [CR] [a] Tacrograf [RW]

tacrolimus 1 mg modified release capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13962W	2	3	..	*179.57	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 5 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13909C	2	3	..	*720.99	31.60	[a] Pharmacor Tacrolimus 5 [CR] [a] Tacrograf [RW]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14066H	2	3	..	*229.93	31.60	Tacrolimus Sandoz [SZ]

tacrolimus 2 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13995N	2	3	..	*658.31	31.60	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13996P	2	2	..	*751.55	31.60	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

Sphingosine-1-phosphate (S1P) receptor modulators

▪ FINGOLIMOD

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10198

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Population criteria:

- Patient must weigh 40 kg or less.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

10093

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Population criteria:

- Patient must weigh 40 kg or less.

fingolimod 250 microgram capsule, 28

11818B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1063.91	31.60	Gilenya [NV]

▪ FINGOLIMOD

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10162

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

10172

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

fingolimod 500 microgram capsule, 28

5262Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	1063.91	31.60	[a] AKM Fingolimod [RW]	[a] Fingolimod Sandoz [SZ]
					[a] Fingolimod SUN [RA]	[a] Fingolimod-Teva [TB]
					[a] FINGOLIS [LR]	[a] Fynod [AF]
					[a] Gilenya [NV]	[a] Pharmacor Fingolimod [CR]

▪ OZANIMOD

Note Ensure that PBS-subsidy is approved for the 920 mcg strength prior to supply of this titration pack. It is advisable to only have the titration pack prescription dispensed at the same time as a prescription for the 920 mcg capsules, or where a supply of the 920 mcg capsules is already in existence (in the case of mid treatment dose interruption).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14017

Moderate to severe ulcerative colitis

Treatment Phase: Dose escalation occurring at initial treatment or re-initiation of treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7

13251K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	589.39	31.60	Zeposia [CJ]

▪ OZANIMOD

Note The initiation pack is intended for use at the commencement of treatment and for re-initiation of therapy following treatment interruption. The first prescription for the 920 microgram capsules should occur under the Initial treatment restriction. Subsequent prescriptions should then occur under the Continuing treatment restriction. If treatment interruption of more than 14 consecutive days occurs for reasons other than lack of efficacy, apply under the Continuing treatment restriction for each of the Initiation pack and 920 microgram capsules. If treatment interruption occurs within the first 14 days, or, for more than 7 consecutive doses between treatment Days 15 to 28, re-apply for an initiation pack under the 'Initial treatment' treatment phase.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10162

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

10172

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

ozanimod 920 microgram capsule, 28

12271W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2220.89	31.60	Zeposia [CJ]

ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7

12278F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	589.39	31.60	Zeposia [CJ]

▪ OZANIMOD

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious

infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

ozanimod 920 microgram capsule, 28

13269J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2220.89	31.60	Zeposia [CJ]

▪ OZANIMOD

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ozanimod 920 microgram capsule, 28

13271L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2220.89	31.60	Zeposia [CJ]

▪ SIPONIMOD

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10955

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; OR
- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory**,** with**/**without assistance**/**support, **AND**
- Patient must have mild disability in at least 3 functional systems; OR
- Patient must have moderate disability in at least 1 functional system.

Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.

Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status.

Note There is no specific Medical Benefits Schedule item for CYP2C9 metabolising enzyme status testing.

Authority required (STREAMLINED)

10953

Multiple sclerosis

Treatment Phase: Continuing treatment (including recommencement of treatment)

Clinical criteria:

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must be ambulatory**,** with**/**without assistance**/**support, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

siponimod 250 microgram tablet, 12

12172P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	240.84	31.60	Mayzent [NV]

siponimod 250 microgram tablet, 120

12160B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2220.90	31.60	Mayzent [NV]

siponimod 2 mg tablet, 28

12158X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2220.89	31.60	Mayzent [NV]

Janus-associated kinase (JAK) inhibitors

▪ BARICITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be

determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

baricitinib 2 mg tablet, 28

13689L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Olumiant [LY]

baricitinib 4 mg tablet, 28

13702E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Olumiant [LY]

▪ BARICITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

baricitinib 2 mg tablet, 28

11442F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Olumiant [LY]

baricitinib 4 mg tablet, 28

11443G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Olumiant [LY]

▪ BARICITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had

insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

baricitinib 2 mg tablet, 28

11437Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1212.40	31.60	Olumiant [LY]

baricitinib 4 mg tablet, 28

11447L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1212.40	31.60	Olumiant [LY]

▪ DEUCRAVACITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15406

Severe chronic plaque psoriasis

Clinical criteria:

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR
- Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

Population criteria:

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to deucravacitinib, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

deucravacitinib 6 mg tablet, 28

13649J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1259.99	31.60	Sotyktu [BQ]

▪ TOFACITINIB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(7) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14697

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tofacitinib 1 mg/mL oral liquid, 240 mL

13738C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults

with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is

based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tofacitinib 5 mg tablet, 56

13730P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological

medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment Phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(7) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14697

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tofacitinib 5 mg tablet, 56

13737B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tofacitinib 5 mg tablet, 56

10511F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tofacitinib 5 mg tablet, 56

11675L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(7) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate prior to initiating treatment with this drug for this condition; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens prior to initiating treatment with this drug for this condition: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

tofacitinib 1 mg/mL oral liquid, 240 mL

13776C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice.

Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under the Balance of supply restriction to complete up to 24 weeks continuing treatment.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under this restriction to complete up to 24 weeks continuing treatment.

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tofacitinib 5 mg tablet, 56

12557X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

tofacitinib 10 mg tablet, 56

12589N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1980.95	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(7) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate prior to initiating treatment with this drug for this condition; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens prior to initiating treatment with this drug for this condition: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

tofacitinib 5 mg tablet, 56

13757C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological

medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment Phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(7) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

tofacitinib 1 mg/mL oral liquid, 240 mL

13770R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had

insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tofacitinib 5 mg tablet, 56

10517M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1212.40	31.60	Xeljanz [PF]

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Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the

baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tofacitinib 5 mg tablet, 56

11690G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR

- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tofacitinib 5 mg tablet, 56

12556W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1212.40	31.60	Xeljanz [PF]

tofacitinib 10 mg tablet, 56

12588M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1980.95	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(7) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

tofacitinib 5 mg tablet, 56

13755Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tofacitinib 5 mg tablet, 56

13349N

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1		3	..	1212.40	31.60	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023, **AND**
- Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tofacitinib 5 mg tablet, 56

13345J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1212.40	31.60	Xeljanz [PF]

▪ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands

Treatment criteria:

- Patient must not be undergoing each of: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions, **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true: (i) there is a change in daily dose, (ii) any remaining PBS repeat prescriptions for the strength that the patient is changing from, is marked as 'cancelled', **AND**
- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**

- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

upadacitinib 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12827D	1	3	..	2077.76	31.60	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12835M	1	3	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Extended induction period (optional) from weeks 12 to 24

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have experienced an inadequate therapeutic benefit following at least one of: (i) dosing with 45 mg daily in the initial 12-week induction period, (ii) dosing with 15 mg daily.

Population criteria:

- Patient must be at least 18 years of age.

upadacitinib 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13762H	1	2	..	2077.76	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where

prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14499

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

upadacitinib 15 mg modified release tablet, 28

14125K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any further authority applications occurring immediately after access through this dose modification listing are not to occur through any of the following Treatment phase listings: (i) Balance of Supply, (ii) Initial Treatment.

Note Dose modification

Where the drug's Product Information indicates variable dosing regimens based on the individual's response/tolerance, apply under this listing to continue treatment with the new strength. Mark any remaining repeat prescriptions for the discontinued strength with the word 'cancelled'. This treatment phase listing recognises that a patient's optimal dose may not always be immediately apparent at the time of treatment initiation and therefore does not require confirmation of an objective, adequate response to the preceding supply of drug.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Dose modification

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy.

upadacitinib 30 mg modified release tablet, 28

13265E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	2077.76	31.60	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

13256Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of

more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

11979L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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upadacitinib 15 mg modified release tablet, 28

12621G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab,

guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

12648Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note If a dose strength change is required, see 'Dose modification' treatment phase to continue treatment at a new dose strength.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance of 24 weeks treatment.

upadacitinib 30 mg modified release tablet, 28

13249H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2077.76	31.60	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

13250J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of

'biological medicine'.
A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.
Treatment cycles:
A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.
Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.
Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.
Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.
An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have commenced treatment with this biological medicine for this condition prior to 1 August 2023, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

upadacitinib 15 mg modified release tablet, 28

13343G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:
Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.
Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

Note Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:
https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

Note The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:
Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94
The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

Note Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the whole body

Clinical criteria:

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**

- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

Population criteria:

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the face and/or hands

Clinical criteria:

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

Population criteria:

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

upadacitinib 30 mg modified release tablet, 28

12836N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	2077.76	31.60	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

12828E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:
Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.
Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

Note Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:
https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

Note The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:
Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94
The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

Note Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the whole body

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the face and/or hands

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**

- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

upadacitinib 30 mg modified release tablet, 28

12829F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2077.76	31.60	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

12831H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an

adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

13350P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

11989B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

12624K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered

complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient - untreated with biological medicine)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

upadacitinib 45 mg modified release tablet, 28

13262B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	2717.45	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by

a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

12625L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1272.78	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR
- The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose:

(i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or

(ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - 'grandfather' arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies were to have been within 4 weeks leading up to commencing the non-PBS subsidised supply of this drug and should have been performed preferably whilst still on conventional treatment, but no longer than 4 weeks following the last dose of conventional treatment.

Where extensive small intestinal disease affecting more than 50 cm of the small intestine applies, the CDAI must have been at least 220 prior to commencing the non-PBS subsidised supply of this drug.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Where prior systemic treatments are specified in this restriction, this is in the context of the time period leading up to the initiation of non-PBS subsidised supply of this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for the Continuing (maintenance) treatment phase

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Continuing (maintenance) treatment aims to provide 24 weeks.

upadacitinib 30 mg modified release tablet, 28

13746L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2077.76	31.60	Rinvoq [VE]

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Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose:

(i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or

(ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional

Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - 'grandfather' arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies were to have been within 4 weeks leading up to commencing the non-PBS subsidised supply of this drug and should have been performed preferably whilst still on conventional treatment, but no longer than 4 weeks following the last dose of conventional treatment.

Where extensive small intestinal disease affecting more than 50 cm of the small intestine applies, the CDAI must have been at least 220 prior to commencing the non-PBS subsidised supply of this drug.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Where prior systemic treatments are specified in this restriction, this is in the context of the time period leading up to the initiation of non-PBS subsidised supply of this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for the Continuing (maintenance) treatment phase

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Continuing (maintenance) treatment aims to provide 24 weeks.

upadacitinib 15 mg modified release tablet, 28

13768P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.78	31.60	Rinvoq [VE]

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Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
Treatment cycle:
A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years;

authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with biological medicine)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The treatment must not have on a previous occasion failed to provide the patient with an adequate response during the current treatment cycle.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In relation to the biological medicine prescribed immediately before this one, provide at least one of the following which is not more than 4 weeks from the last administered dose:

(i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or

(ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; or

(iii) confirmation that a severe intolerance occurred that resulted in the cessation of treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR

- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Provide at least one of the following:

(i) the current Crohn Disease Activity Index (CDAI) score, including the date this score was calculated on;

(ii) confirmation that there is a documented history of intestinal inflammation plus diagnostic imaging/surgical evidence of at least one of: (a) short gut syndrome, (b) ileostomy, (c) colostomy;

(iii) confirmation that there is a documented history and radiological evidence of intestinal inflammation from extensive small intestinal disease affecting more than 50 cm of the small intestine where the CDAI score is at least 220, but below 300.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - 'grandfather' arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies were to have been within 4 weeks leading up to commencing the non-PBS subsidised supply of this drug and should have been performed preferably whilst still on conventional treatment, but no longer than 4 weeks following the last dose of conventional treatment.

Where extensive small intestinal disease affecting more than 50 cm of the small intestine applies, the CDAI must have been at least 220 prior to commencing the non-PBS subsidised supply of this drug.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Where prior systemic treatments are specified in this restriction, this is in the context of the time period leading up to the initiation of non-PBS subsidised supply of this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for Initial (induction) treatment phases

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Initial (induction) treatment phases and 'Extended induction' treatment phases for this benefit aim to provide 12 weeks treatment duration.

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upadacitinib 45 mg modified release tablet, 28

13771T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2717.45	31.60	Rinvoq [VE]

Monoclonal antibodies

▪ OFATUMUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10172

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device

12641H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2184.80	31.60	Kesimpta [NV]

▪ OFATUMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note The intent of this listing is to provide doses at weeks 0, 1 and 2. For treatment at week 4 and beyond, see the 'Continuing treatment' listing.

Authority required (STREAMLINED)

10162

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device

12642J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*6337.47	31.60	Kesimpta [NV]

▪ VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment

discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply - subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12620F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1747.77	31.60	Entyvio [TK]

▪ VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
Treatment cycle:
A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment with subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12638E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1747.77	31.60	Entyvio [TK]

▪ VEDOLIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional

Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12644L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1747.77	31.60	Entyvio [TK]

▪ VEDOLIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply - subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12647P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1747.77	31.60	Entyvio [TK]

▪ VEDOLIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12639F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1747.77	31.60	Entyvio [TK]

▪ VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that

contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
Treatment cycle:
A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
An exception to this 5 year break clause applies where:
(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
(ii) the patient has never been prescribed the newly listed biological medicine; and
(iii) the prescribed biological medicine is the newly listed biological medicine.
Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).
Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(a) Initial 1
Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.
(b) Initial 2
Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.
(c) Initial 3
Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.
(d) Continuing treatment
Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.
(e) Balance of supply
Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12654B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1747.77	31.60	Entyvio [TK]

Mammalian target of rapamycin (mTOR) kinase inhibitors

▪ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

everolimus 250 microgram tablet, 60

8840G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	179.99	31.60	[a] Certican [NV]	[a] Everocan [CR]

everolimus 500 microgram tablet, 60

8841H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	307.87	31.60	[a] Certican [NV]	[a] Everocan [CR]

everolimus 750 microgram tablet, 60

8842J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*872.29	31.60	[a] Certican [NV]	[a] Everocan [CR]

everolimus 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9352F	2	3	..	*1150.77	31.60	[a] Certican [NV]	[a] Everocan [CR]

▪ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

everolimus 750 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14040Y	4	3	..	*1736.15	31.60	[a] Certican [NV]	[a] Everocan [CR]

everolimus 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13941R	4	3	..	*2284.31	31.60	[a] Certican [NV]	[a] Everocan [CR]

▪ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

sirolimus 1 mg/mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8725F	‡1	3	..	521.99	31.60	Rapamune [PF]

sirolimus 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8984W	1	3	..	340.11	31.60	Rapamune [PF]

sirolimus 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8724E	1	3	..	653.78	31.60	Rapamune [PF]

sirolimus 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8833X	1	3	..	1270.70	31.60	Rapamune [PF]

▪ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

sirolimus 1 mg/mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13885T	‡2	3	..	*1035.53	31.60	Rapamune [PF]

sirolimus 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13860L	2	3	..	*671.77	31.60	Rapamune [PF]

sirolimus 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14072P	2	3	..	*1299.09	31.60	Rapamune [PF]

sirolimus 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13886W	2	3	..	*2512.73	31.60	Rapamune [PF]

Dihydroorotate dehydrogenase (DHODH) inhibitors

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Restricted benefit

Severe active psoriatic arthritis

Clinical criteria:

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR

- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

5449T

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	26.23	27.68	[a] APO-LEFLUNOMIDE [TX] [a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]	[a] Arabloc [AV] [a] Ataris 10 [AF] [a] Leflunomide generichealth [HQ]

leflunomide 20 mg tablet, 30

5450W

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	32.91	31.60	[a] APO-LEFLUNOMIDE [TX] [a] Ataris 20 [AF] [a] Leflunomide generichealth [HQ]	[a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Restricted benefit

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

8374R

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	26.23	27.68	[a] APO-LEFLUNOMIDE [TX] [a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]	[a] Arabloc [AV] [a] Ataris 10 [AF] [a] Leflunomide generichealth [HQ] [a] Lunava 10 [RW]

leflunomide 20 mg tablet, 30

8375T

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	32.91	31.60	[a] APO-LEFLUNOMIDE [TX] [a] Ataris 20 [AF] [a] Leflunomide generichealth [HQ] [a] Lunava 20 [RW]	[a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Restricted benefit

Severe active rheumatoid arthritis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

13940Q

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2		5	..	*39.01	31.60	[a] APO-LEFLUNOMIDE [TX] [a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]	[a] Arabloc [AV] [a] Ataris 10 [AF] [a] Leflunomide generichealth [HQ] [a] Lunava 10 [RW]

leflunomide 20 mg tablet, 30

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2		5	..	*52.37	31.60	[a] APO-LEFLUNOMIDE [TX]	[a] Arava [SW]

14069L

[a] Ataris 20 [AF]	[a] Leflunomide APOTEX [GX]
[a] Leflunomide generichealth [HQ]	[a] Leflunomide Sandoz [SZ]
[a] Lunava 20 [RW]	

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Restricted benefit

Severe active psoriatic arthritis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

14068K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*39.01	31.60	[a] APO-LEFLUNOMIDE [TX]	[a] Arabloc [AV]
					[a] Arava [SW]	[a] Ataris 10 [AF]
					[a] Leflunomide APOTEX [GX]	[a] Leflunomide generichealth [HQ]
					[a] Leflunomide Sandoz [SZ]	

leflunomide 20 mg tablet, 30

13998R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*52.37	31.60	[a] APO-LEFLUNOMIDE [TX]	[a] Arava [SW]
					[a] Ataris 20 [AF]	[a] Leflunomide APOTEX [GX]
					[a] Leflunomide generichealth [HQ]	[a] Leflunomide Sandoz [SZ]

▪ TERIFLUNOMIDE

Caution Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10150

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

10199

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

teriflunomide 14 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2898M	1	5	..	179.79	31.60	[a] APO-TERIFLUNOMIDE [TX] [a] TERIFLAGIO [RW] [a] Teriflunomide GH [GQ] [a] Terimide [AF]	[a] Pharmacor Teriflunomide [CR] [a] Teriflunomide Dr.Reddy's [RZ] [a] Teriflunomide Sandoz [SZ]

Other immunosuppressants

▪ AZATHIOPRINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

azathioprine 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2688L NP	1	5	..	23.48	24.93	[a] APO-Azathioprine [TX] [a] NOUMED AZATHIOPRINE [VO]	[a] Azathioprine Sandoz [SZ]
			[B]5.00	28.48	24.93	[a] Imuran [AS]	

azathioprine 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2687K NP	1	5	..	30.53	31.60	[a] APO-Azathioprine [TX] [a] Azathioprine Sandoz [SZ] [a] NOUMED AZATHIOPRINE [VO]	[a] Azapin [RW] [a] Imazan [ZS] [a] Thioprine 50 [AF]
			[B]5.00	35.53	31.60	[a] Imuran [AS]	

▪ DIMETHYL FUMARATE

Authority required (STREAMLINED)

10139

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2943X	2	..	..	*356.75	31.60	[a] APO-DIMETHYL FUMARATE [XT] [a] Dimethyl Fumarate Sandoz [SZ] [a] Tecfidera [BD]	[a] Dimethyl Fumarate MSN [LR] [a] Pharmacor Dimethyl Fumarate [CR]

dimethyl fumarate 240 mg enteric capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2966D	1	5	..	680.07	31.60	[a] APO-DIMETHYL FUMARATE [XT] [a] Dimethyl Fumarate Sandoz [SZ] [a] Tecfidera [BD]	[a] Dimethyl Fumarate MSN [LR] [a] Pharmacor Dimethyl Fumarate [CR] [a] Trazent [AF]

▪ DIMETHYL FUMARATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10140

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

2896K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*356.75	31.60	[a] APO-DIMETHYL FUMARATE [XT] [a] Dimethyl Fumarate Sandoz [SZ] [a] Tecfidera [BD]	[a] Dimethyl Fumarate MSN [LR] [a] Pharmacor Dimethyl Fumarate [CR]

▪ DIROXIMEL FUMARATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

13072

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

13034

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

diroximel fumarate 231 mg enteric capsule, 120

13059H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	715.73	31.60	Vumerity [BD]

▪ METHOTREXATE

methotrexate 10 mg tablet, 15

2272N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	25.56	27.01	[a] ARX-Methotrexate [XT] [a] Methoblastin [PF]	[a] Chexate [OX]

methotrexate 2.5 mg tablet, 30

1622J

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.29	20.74	[a] ARX-Methotrexate [XT] [a] Methoblastin [PF]	[a] Chexate [OX]

▪ METHOTREXATE

Restricted benefit

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1623K NP	1	2	..	53.78	31.60	[a] ARX-Methotrexate [XT] [a] Methoblastin [PF]	[a] Chexate [OX]

▪ METHOTREXATE

Authority required (STREAMLINED)

7488

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)

7518

Severe psoriasis

Clinical criteria:

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11275K NP	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11283W NP	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11268C NP	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11288D NP	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11295L NP	4	5	..	*90.87	31.60	Trexject [LM]

▪ METHOTREXATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

15068

Severe active juvenile idiopathic arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14091P	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14089M	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14102F	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14097Y	4	5	..	*90.87	31.60	Trexject [LM]

methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14103G	4	5	..	*90.87	31.60	Trexject [LM]

▪ PIRFENIDONE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

pirfenidone 801 mg tablet, 90

11410M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	608.13	31.60	[a] Pirfenidet [AF]	[a] Pirfenidone Ameda [XT]
					[a] Pirfenidone Dr.Reddy's [RZ]	[a] Pirfenidone Sandoz [SZ]

▪ PIRFENIDONE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pirfenidone 267 mg tablet, 90

11406H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	5	..	*608.10	31.60	[a] Pirfenidet [AF]	[a] Pirfenidone Ameda [XT]
					[a] Pirfenidone Dr.Reddy's [RZ]	[a] Pirfenidone Sandoz [SZ]

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Acetic acid derivatives and related substances

DICLOFENAC

diclofenac sodium 100 mg suppository, 20

1302M (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*29.89	31.34	Voltaren 100 [NV]

diclofenac sodium 100 mg suppository, 20

5079H (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.89	31.34	Voltaren 100 [NV]

diclofenac sodium 25 mg enteric tablet, 50

1299J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*18.89	20.34	[a] APO-Diclofenac [TX]	[a] Clonac 25 [RW]
					[a] Diclofenac Sandoz [SZ]	[a] Fenac EC [AL]

			[B]3.40	*22.29	20.34	[a] Voltaren 25 [NV]	

diclofenac sodium 25 mg enteric tablet, 50

5076E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	2	..	..	*18.89	20.34	[a] APO-Diclofenac [TX] [a] Diclofenac Sandoz [SZ]	[a] Clonac 25 [RW] [a] Fenac EC [AL]
			[B]3.40	*22.29	20.34	[a] Voltaren 25 [NV]	

diclofenac sodium 50 mg enteric tablet, 50

1300K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.37	17.82	[a] APO-Diclofenac [TX] [a] Diclofenac Sandoz [SZ]	[a] Clonac 50 [RW] [a] Fenac EC [AL]
			[B]3.23	19.60	17.82	[a] Voltaren 50 [NV]	

diclofenac sodium 50 mg enteric tablet, 50

5077F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.37	17.82	[a] APO-Diclofenac [TX] [a] Diclofenac Sandoz [SZ]	[a] Clonac 50 [RW] [a] Fenac EC [AL]
			[B]3.23	19.60	17.82	[a] Voltaren 50 [NV]	

▪ INDOMETACIN

indometacin 100 mg suppository, 20

2757D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*27.45	28.90	Indocid [AS]

indometacin 100 mg suppository, 20

5128X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*27.45	28.90	Indocid [AS]

▪ INDOMETACIN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

indometacin 25 mg capsule, 50

2454E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*20.13	21.58	[a] Arthrexin [AF]
			[B]4.04	*24.17	21.58	[a] Indocid [AS]

▪ INDOMETACIN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

indometacin 25 mg capsule, 50

5126T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*20.13	21.58	[a] Arthrexin [AF]
			[B]4.04	*24.17	21.58	[a] Indocid [AS]

Oxicams

▪ MELOXICAM

Note Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

meloxicam 7.5 mg capsule, 30

8887R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	16.97	18.42	[a] APO-Meloxicam [TX] [a] Meloxicam Sandoz [SZ] [a] Moxicam [AF]	[a] MELOBIC [RF] [a] Movalis 7.5 [RW]
		[B]2.82	19.79	18.42	[a] Mobic [BY]	

meloxicam 7.5 mg tablet, 30

8561N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	16.97	18.42	[a] APX-Meloxicam [TY] [a] MELOBIC [RF] [a] Meloxicam Sandoz [SZ] [a] Movalis 7.5 [RW] [a] Pharmacor Meloxicam 7.5 [CR]	[a] CIPLA MELOXICAM 7.5 [LR] [a] Meloxibell [GQ] [a] Meloxicam Viatris [AL] [a] Moxicam 7.5 [AF]
		[B]2.82	19.79	18.42	[a] Mobic [BY]	

▪ MELOXICAM

Note Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

meloxicam 15 mg capsule, 30

8888T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	17.67	19.12	[a] APO-Meloxicam [TX] [a] Meloxicam Sandoz [SZ] [a] Moxicam [AF]	[a] MELOBIC [RF] [a] Movalis 15 [RW]
		[B]2.88	20.55	19.12	[a] Mobic [BY]	

meloxicam 15 mg tablet, 30

8562P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	17.67	19.12	[a] APX-Meloxicam [TY] [a] MELOBIC [RF] [a] Meloxicam Sandoz [SZ] [a] Movalis 15 [RW] [a] Pharmacor Meloxicam 15 [CR]	[a] CIPLA MELOXICAM 15 [LR] [a] Meloxibell [GQ] [a] Meloxicam Viatris [AL] [a] Moxicam 15 [AF]
		[B]2.88	20.55	19.12	[a] Mobic [BY]	

▪ PIROXICAM

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

piroxicam 10 mg capsule, 50

1897W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	18.02	19.47	APO-Piroxicam [TX]

piroxicam 10 mg capsule, 50

5203W (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	18.02	19.47	APO-Piroxicam [TX]

piroxicam 20 mg capsule, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1898X NP	1	3	..	16.83	18.28	APO-Piroxicam [TX]

piroxicam 20 mg capsule, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5204X DP	1	..	..	16.83	18.28	APO-Piroxicam [TX]

piroxicam 20 mg dispersible tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1896T NP	1	3	..	17.82	19.27	Feldene-D [PF]

piroxicam 20 mg dispersible tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5202T DP	1	..	..	17.82	19.27	Feldene-D [PF]

Propionic acid derivatives

▪ IBUPROFEN

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3192B NP MW	1	..	..	16.15	17.60	[a] APO-Ibuprofen 400 [TX]	[a] MEDICHOICE Ibuprofen 400 mg [NB]
			[B]2.51	18.66	17.60	[a] Brufen [GO]	

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5124Q DP	1	..	..	16.15	17.60	[a] APO-Ibuprofen 400 [TX]	[a] MEDICHOICE Ibuprofen 400 mg [NB]
			[B]2.51	18.66	17.60	[a] Brufen [GO]	

▪ IBUPROFEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3190X NP	3	3	..	*21.54	22.99	[a] APO-Ibuprofen 400 [TX]	[a] MEDICHOICE Ibuprofen 400 mg [NB]
			[B]7.53	*29.07	22.99	[a] Brufen [GO]	

▪ IBUPROFEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5123P DP	3	..	..	*21.54	22.99	[a] APO-Ibuprofen 400 [TX]	[a] MEDICHOICE Ibuprofen 400 mg [NB]
			[B]7.53	*29.07	22.99	[a] Brufen [GO]	

▪ KETOPROFEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

ketoprofen 200 mg modified release capsule, 28

1590Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	21.02	22.47	[a] Oruvail SR [AV]
		[B]2.88	23.90	22.47	[a] Orudis SR 200 [SW]

NP

ketoprofen 200 mg modified release capsule, 28

5136H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	21.02	22.47	[a] Oruvail SR [AV]
		[B]2.88	23.90	22.47	[a] Orudis SR 200 [SW]

DP

▪ NAPROXEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen 1 g modified release tablet, 28

1615B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	19.28	20.73	[a] Proxen SR 1000 [IY]
		[B]2.35	21.63	20.73	[a] Naprosyn SR1000 [IX]

NP

naproxen 250 mg tablet, 50

1674D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*21.89	23.34	Naprosyn [IX]

NP

naproxen 750 mg modified release tablet, 28

1614Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	17.93	19.38	[a] Proxen SR 750 [IY]
		[B]2.35	20.28	19.38	[a] Naprosyn SR750 [IX]

NP

▪ NAPROXEN

Authority required (STREAMLINED)

4159

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

Authority required (STREAMLINED)

4124

Bone pain

Clinical criteria:

- The condition must be due to malignant disease, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

naproxen 125 mg/5 mL oral liquid, 474 mL

1658G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	124.15	31.60	Phebra Naproxen Suspension [FF]

NP

▪ NAPROXEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen 1 g modified release tablet, 28

5179N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	19.28	20.73	[a] Proxen SR 1000 [IY]
		[B]2.35	21.63	20.73	[a] Naprosyn SR1000 [IX]

DP

naproxen 250 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5176K DP	2	..	..	*21.89	23.34	Naprosyn [IX]

naproxen 750 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5178M DP	1	..	..	17.93	19.38	[a] Proxen SR 750 [IY]
			[B]2.35	20.28	19.38	[a] Naprosyn SR750 [IX]

▪ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen sodium 550 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1795L NP	1	3	..	18.42	19.87	[a] Crysanal [IY]
			[B]2.85	21.27	19.87	[a] Anaprox 550 [IX]

▪ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen sodium 550 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5186Y DP	1	..	..	18.42	19.87	[a] Crysanal [IY]
			[B]2.85	21.27	19.87	[a] Anaprox 550 [IX]

Fenamates

▪ MEFENAMIC ACID

Restricted benefit

Dysmenorrhoea

Restricted benefit

Menorrhagia

mefenamic acid 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1824B NP	1	2	..	19.69	21.14	[a] FEMIN [XT]
			[B]2.07	21.76	21.14	[a] Ponstan [PF]

Coxibs

▪ CELECOXIB

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

celecoxib 100 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8439E NP	1	3	..	17.87	19.32	[a] APX-Celecoxib [TW]	[a] Blooms the Chemist Celecoxib [IB]
						[a] Celaxib [AF]	[a] Celebrex [UJ]
						[a] Celecoxib APOTEX [TY]	[a] Celecoxib GH [GQ]
						[a] Celecoxib Sandoz [SZ]	[a] Celexi [RW]
						[a] NOUMED CELECOXIB [VO]	

celecoxib 200 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8440F NP	1	3	..	17.87	19.32	[a] APX-Celecoxib [TW]	[a] Blooms the Chemist Celecoxib [IB]
						[a] Celaxib [AF]	[a] Celebrex [UJ]
						[a] Celecoxib APOTEX [TY]	[a] Celecoxib GH [GQ]
						[a] Celecoxib Sandoz [SZ]	[a] Celexi [RW]
						[a] NOUMED CELECOXIB [VO]	

SPECIFIC ANTIRHEUMATIC AGENTS

Quinolines

▪ HYDROXYCHLOROQUINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

hydroxychloroquine sulfate 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1512N NP	1	1	..	27.52	28.97	[a] APO- Hydroxychloroquine [TX]	[a] Hequinel [RW]
						[a] Hydroxychloroquine GH [GQ]	[a] Plaquenil [SW]

Gold preparations

▪ AURANOFIN

Caution Regular blood and urine checks are essential.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

auranofin 3 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2022K NP	1	5	..	905.31	31.60	Ridaura [BZ]

auranofin 3 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1095P NP	1	5	..	165.80	31.60	Ridaura [GH]

Penicillamine and similar agents

▪ PENICILLAMINE

Caution Regular blood and urine checks are essential.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

penicillamine 125 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2721F NP	1	1	..	64.41	31.60	D-Penamine [AL]

penicillamine 250 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2838J NP	1	1	..	77.47	31.60	D-Penamine [AL]

▪ PENICILLAMINE

Caution Regular blood and urine checks are essential.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

penicillamine 125 mg tablet, 100

13458H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*115.45	31.60	D-Penamine [AL]

penicillamine 250 mg tablet, 100

13425N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*142.89	31.60	D-Penamine [AL]

▪ MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

▪ BACLOFEN

baclofen 10 mg tablet, 100

2729P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.44	24.89	[a] APO-Baclofen [TX] [a] Lioresal 10 [NV]	[a] Clofen 10 [AF] [a] Stelax 10 [RW]

baclofen 25 mg tablet, 100

2730Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	35.27	31.60	[a] APO-Baclofen [TX] [a] Lioresal 25 [NV]	[a] Clofen 25 [AF] [a] Stelax 25 [RW]

▪ BACLOFEN

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

baclofen 10 mg tablet, 100

13522Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*33.43	31.60	[a] APO-Baclofen [TX] [a] Lioresal 10 [NV]	[a] Clofen 10 [AF] [a] Stelax 10 [RW]

baclofen 25 mg tablet, 100

13359D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*57.09	31.60	[a] APO-Baclofen [TX] [a] Lioresal 25 [NV]	[a] Clofen 25 [AF] [a] Stelax 25 [RW]

MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

Dantrolene and derivatives

▪ DANTROLENE

Restricted benefit

Chronic spasticity

dantrolene sodium hemiheptahydrate 25 mg capsule, 100

1779P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	162.81	31.60	Dantrium [PF]

▪ ANTIGOUT PREPARATIONS

ANTIGOUT PREPARATIONS

Preparations inhibiting uric acid production

▪ ALLOPURINOL

Note The dose should be adjusted in accordance with renal function.

allopurinol 100 mg tablet, 200

2600W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	18.32	19.77	[a] Allopurinol APOTEX [GX] [a] Allosig [RF] [a] Progout 100 [AF]	[a] Allopurinol Sandoz [SZ] [a] NOUMED ALLOPURINOL [VO]
		[B]5.62	23.94	19.77	[a] Zyloprim [RW]	

allopurinol 300 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2604C NP	1	2	..	17.22	18.67	[a] Allopurinol APOTEX [GX] [a] Allosig [RF] [a] Progout 300 [AF]	[a] Allopurinol Sandoz [SZ] [a] NOUMED ALLOPURINOL [VO]
			[B]5.64	22.86	18.67	[a] Zyloprim [RW]	

▪ ALLOPURINOL

Note The dose should be adjusted in accordance with renal function.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

allopurinol 100 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13358C NP	2	2	..	*23.19	24.64	[a] Allopurinol APOTEX [GX] [a] Allosig [RF] [a] Progout 100 [AF]	[a] Allopurinol Sandoz [SZ] [a] NOUMED ALLOPURINOL [VO]
			[B]11.24	*34.43	24.64	[a] Zyloprim [RW]	

allopurinol 300 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13575L NP	2	2	..	*20.99	22.44	[a] Allopurinol APOTEX [GX] [a] Allosig [RF] [a] Progout 300 [AF]	[a] Allopurinol Sandoz [SZ] [a] NOUMED ALLOPURINOL [VO]
			[B]11.28	*32.27	22.44	[a] Zyloprim [RW]	

▪ FEBUXOSTAT

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

8921

Chronic gout

Clinical criteria:

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

febuxostat 80 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10445R NP	1	5	..	51.32	31.60	Adenuric [FK]

▪ FEBUXOSTAT

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14313

Chronic gout

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

febuxostat 80 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13519M NP	2	5	..	*89.19	31.60	Adenuric [FK]

Preparations increasing uric acid excretion

▪ PROBENECID

probenecid 500 mg tablet, 100

1940D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	75.82	31.60	Pro-Cid [FF]

NP

▪ PROBENECID

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

probenecid 500 mg tablet, 100

13942T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*139.41	31.60	Pro-Cid [FF]

NP

Preparations with no effect on uric acid metabolism

▪ COLCHICINE

colchicine 500 microgram tablet, 30

3410L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.15	18.60	[a] Colcine [CR]	[a] Lengout [LN]
		[B]2.02	19.17	18.60	[a] Colgout [AS]	

NP

▪ DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

▪ ALENDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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alendronate 70 mg tablet, 4

8511Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.37	18.82	[a] Alendronate Sandoz [SZ] [a] Fonat [AL]	[a] APO-Alendronate [TX]

NP

▪ ALENDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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alendronate 70 mg tablet, 4

13499L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*21.29	22.74	[a] Alendronate Sandoz [SZ] [a] Fonat [AL]	[a] APO-Alendronate [TX]

NP

▪ IBANDRONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

ibandronate 50 mg tablet, 28

9357L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	219.38	31.60	Bondronat [IX]

NP

▪ PAMIDRONATE DISODIUM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Symptomatic Paget disease of bone

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8461H NP	4	..	..	*72.87	31.60	Pamisol [PF]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8462J NP	2	..	..	*72.89	31.60	Pamisol [PF]

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8463K NP	1	..	..	72.88	31.60	Pamisol [PF]

▪ RISEDRONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Symptomatic Paget disease of bone

risedronate sodium 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8482K NP	1	1	..	180.66	31.60	Actonel [TT]

▪ RISEDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

risedronate sodium 150 mg tablet, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9391G NP	1	5	..	35.60	31.60	[a] Actonel Once-a-Month [TT]	[a] APO-Risedronate [TX]

risedronate sodium 35 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8621R NP	1	5	..	33.88	31.60	[a] APO-Risedronate [TX]	[a] Risedronate Sandoz [SZ]

risedronate sodium 35 mg enteric tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8972F NP	1	5	..	33.88	31.60	Actonel EC [TT]

risedronate sodium 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8481J NP	1	5	..	37.47	31.60	Actonel [TT]

▪ RISEDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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risedronate sodium 150 mg tablet, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13488X NP	2	5	..	*57.75	31.60	[a] Actonel Once-a-Month [TT]	[a] APO-Risedronate [TX]

risedronate sodium 35 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13459J NP	2	5	..	*54.31	31.60	[a] APO-Risedronate [TX]	[a] Risedronate Sandoz [SZ]

risedronate sodium 35 mg enteric tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13364J NP	2	5	..	*54.31	31.60	Actonel EC [TT]

risedronate sodium 5 mg tablet, 28

13360E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*61.49	31.60	Actonel [TT]

NP

▪ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5710

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9350D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	74.99	31.60	[a] Aclasta [HX] [a] Zoledasta [TX] [a] Zoledronic Acid SUN [RA]	[a] Osteovan [SZ] [a] Zoledronate-RDY 5 [RI]

▪ ZOLEDRONIC ACID

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6308

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6313

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6318

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9288W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	74.99	31.60	[a] Aclasta [HX] [a] Zoledasta [TX] [a] Zoledronic Acid SUN [RA]	[a] Osteovan [SZ] [a] Zoledronate-RDY 5 [RI]

Bisphosphonates, combinations

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

9183H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18.98	20.43	Fosamax Plus 70 mg/140 mcg [MQ]

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

15032

Corticosteroid-induced osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

14898

Osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

14993

Established osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

13835E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*24.51	25.96	Fosamax Plus 70 mg/140 mcg [MQ]

NP

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

Authority required (STREAMLINED)

6307

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6320

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6315

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

9012H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18.98	20.43	Fosamax Plus [MQ]

NP

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

Authority required (STREAMLINED)

15024

Corticosteroid-induced osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

15011

Osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

15035

Established osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

14003B

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*24.51	25.96	Fosamax Plus [MQ]

Other drugs affecting bone structure and mineralization

▪ CALCITRIOL

Authority required (STREAMLINED)

5401

Hypocalcaemia

Clinical criteria:

- The condition must be due to renal disease.

Authority required (STREAMLINED)

5255

Hypoparathyroidism

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5402

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

2502Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	29.58	31.03	[a] APO-Calcitriol [TX] [a] CALITROL [XT] [a] Sical [AF]	[a] Calciprox [ZS] [a] Kosteo [RW]
			[B]2.29	31.87	31.03	[a] Rocaltrol [IX]	

▪ CALCITRIOL

Authority required (STREAMLINED)

14322

Hypocalcaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

Authority required (STREAMLINED)

14287

Hypoparathyroidism

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

14231

Hypophosphataemic rickets

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

14296

Vitamin D-resistant rickets

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

14259

Established osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

13457G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*45.71	31.60	[a] APO-Calcitriol [TX] [a] CALITROL [XT] [a] Sical [AF]	[a] Calciprox [ZS] [a] Kosteo [RW]
			[B]4.58	*50.29	31.60	[a] Rocaltrol [IX]	

▪ DENOSUMAB

Note Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4504

Giant cell tumour of bone

Clinical criteria:

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

Population criteria:

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

denosumab 120 mg/1.7 mL injection, 1.7 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10061M NP	1	5	..	462.13	31.60	Xgeva [AN]

▪ DENOSUMAB

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4158

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

Authority required (STREAMLINED)

4150

Bone metastases

Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

denosumab 120 mg/1.7 mL injection, 1.7 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5110Y NP	1	5	..	462.13	31.60	Xgeva [AN]

▪ DENOSUMAB

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6548

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6524

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

denosumab 60 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5457F NP	1	..	..	251.97	31.60	Prolia [AN]

▪ RALOXIFENE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6314

Established post-menopausal osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

raloxifene hydrochloride 60 mg tablet, 28

8363E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.30	31.60	[a] Fixta 60 [ZS] [a] Raloxifene GH [GQ]	[a] RALOVISTA [RF]
			[B]4.09	34.39	31.60	[a] Evista [LY]	

▪ RALOXIFENE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

14274

Established post-menopausal osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

raloxifene hydrochloride 60 mg tablet, 28

13426P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*47.15	31.60	[a] Fixta 60 [ZS] [a] Raloxifene GH [GQ]	[a] RALOVISTA [RF]
			[B]8.18	*55.33	31.60	[a] Evista [LY]	

▪ ROMOSOZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe established osteoporosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised teriparatide; OR
- Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

Treatment criteria:

- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy.

Treatment criteria:

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes

12301K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	406.13	31.60	Evenity [AN]

▪ TERIPARATIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12492

Severe established osteoporosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

Authority required (STREAMLINED)

12270

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

14093R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	177.30	31.60	[a] Teriparatide Lupin [GQ]	[a] Terrosa [FX]

▪ VOSORITIDE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Achondroplasia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

Treatment criteria:

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Appropriate genetic testing constitutes testing for FGFR3 gene mutation.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

Authority required

Achondroplasia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS subsidised vosoritide treatment for this condition, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

Treatment criteria:

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

vosoritide 400 microgram injection [10 vials] (&) inert substance diluent [10 x 0.5 mL syringes], 1 pack

13275Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*27840.60	31.60	Voxzogo [IO]

vosoritide 560 microgram injection [10 vials] (&) inert substance diluent [10 x 0.7 mL syringes], 1 pack

13274P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*27840.60	31.60	Voxzogo [IO]

vosoritide 1.2 mg injection [10 vials] (&) inert substance diluent [10 x 0.6 mL syringes], 1 pack

13270K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*27840.60	31.60	Voxzogo [IO]

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

CODEINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

codeine phosphate hemihydrate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12054K DP	0.5	..	..	*23.08	24.53	Aspen Pharma Pty Ltd [AS]

CODEINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

codeine phosphate hemihydrate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5063L DP	1	..	..	23.20	24.65	Aspen Pharma Pty Ltd [AS]

CODEINE

Caution The risk of drug dependence is high.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

codeine phosphate hemihydrate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12065B NP	0.5	..	..	*23.08	24.53	Aspen Pharma Pty Ltd [AS]

CODEINE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

codeine phosphate hemihydrate 30 mg tablet, 20

1214X

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.20	24.65	Aspen Pharma Pty Ltd [AS]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

hydromorphone hydrochloride 2 mg tablet, 20

12045Y (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	..	..	*24.46	25.91	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

12032G (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	..	..	*25.86	27.31	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

12010D (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	..	..	*31.08	31.60	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

14080C (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	435.42	31.60	pms-HYDROmorphone [DZ]

hydromorphone hydrochloride 2 mg tablet, 20

5115F (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	25.42	26.87	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

5116G (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	27.69	29.14	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

5117H (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	36.10	31.60	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

hydromorphone hydrochloride 2 mg tablet, 20

12047C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	..	..	*24.46	25.91	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12046B NP	0.5	..	..	*25.86	27.31	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12016K NP	0.5	..	..	*31.08	31.60	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12559B DP	1	..	..	351.38	31.60	[a] Hikma [LM]

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13799G DP	1	..	..	435.42	31.60	[a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

14076W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	435.42	31.60	pms-HYDROmorphone [DZ]

hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

8421F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	26.92	28.37	[a] Dilaudid-HP [MF]	[a] Hydromorphone-hameln-HP [HW]
					[a] HYDROMORPHONE JUNO-HP [JU]	[a] MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ]

hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

8420E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	24.89	26.34	[a] Dilaudid [MF]	[a] Hydromorphone-hameln [HW]
					[a] HYDROMORPHONE JUNO [JU]	[a] MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ]

hydromorphone hydrochloride 2 mg tablet, 20

8541M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	25.42	26.87	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

8542N (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	27.69	29.14	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

8543P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	36.10	31.60	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Note Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

12582F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	351.38	31.60	[a] Hikma [LM]

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

13796D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	435.42	31.60	[a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

5169C DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.55	28.00	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

5170D DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	28.65	30.10	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

10858L DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.11	27.56	Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

morphine sulfate 10 mg/5 mL oral solution, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13750Q DP	2	..	..	*148.74	31.60	[a] Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

morphine sulfate 10 mg/5 mL oral solution, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13740E DP	0.67	..	..	*95.46	31.60	[a] Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

morphine sulfate 2 mg/mL oral solution, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13747M DP	2	..	..	*110.28	31.60	[a] Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

morphine sulfate 2 mg/mL oral solution, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13760F DP	0.4	..	..	*76.66	31.60	[a] Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5168B DP	1	..	..	23.79	25.24	[a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10863R DP	1	..	..	23.58	25.03	[a] Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand RA-Morph (NZ) can be substituted for Ordine 5 in case of shortage.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14203M DP	1	..	..	104.85	31.60	[a] RA-Morph (NZ) [WZ]

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5238Q DP	1	..	..	33.26	31.60	[a] Ordine 5 [XT]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL

5237P (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	31.92	31.60	[a] Ordine 2 [XT]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Morphini HCl Streuli or the brand RA-Morph (NZ) can be substituted for pharmaceutical benefits that have the brand Ordine 10 in case of a shortage.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL

14077X (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*566.44	31.60	[a] Morphini HCl Streuli [DZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

14204N (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	154.95	31.60	[a] RA-Morph (NZ) [WZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

5239R (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	35.81	31.60	[a] Ordine 10 [XT]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

1645N (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.55	28.00	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

1647Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	28.65	30.10	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

10874H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.11	27.56	Morphine Juno [JU]

morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

10869C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	30.96	31.60	Morphine Juno [JU]

morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules

10878M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	39.04	31.60	Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

Restricted benefit

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Cancer pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 10 mg tablet, 20

8669G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.35	24.80	Sevredol [MF]

morphine sulfate pentahydrate 20 mg tablet, 20

8670H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	24.10	25.55	Sevredol [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate 10 mg/5 mL oral solution, 100 mL

13761G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*148.74	31.60	[a] Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

morphine sulfate 10 mg/5 mL oral solution, 300 mL

13756B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.67	..	..	*95.46	31.60	[a] Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

morphine sulfate 2 mg/mL oral solution, 100 mL

13753W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*110.28	31.60	[a] Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

morphine sulfate 2 mg/mL oral solution, 500 mL

13749P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.4	..	..	*76.66	31.60	[a] Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

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Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

1644M NP MW

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.79	25.24	[a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

10864T NP MW

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.58	25.03	[a] Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

Authority required

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 200 mg modified release tablet, 28

12055L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	121.43	31.60	MS Contin [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand RA-Morph (NZ) can be substituted for Ordine 5 in case of shortage.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR

- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

14220K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	104.85	31.60	[a] RA-Morph (NZ) [WZ]

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

2123R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	33.26	31.60	[a] Ordine 5 [XT]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 10 mg modified release capsule, 28

8349K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	28.31	29.76	Kapanol [YN]

morphine sulfate pentahydrate 100 mg modified release capsule, 28

2841M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	60.75	31.60	Kapanol [YN]

morphine sulfate pentahydrate 120 mg modified release capsule, 14

8494C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	49.53	31.60	MS Mono [MF]

morphine sulfate pentahydrate 20 mg modified release capsule, 28

2839K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	29.21	30.66	Kapanol [YN]

morphine sulfate pentahydrate 30 mg modified release capsule, 14

8491X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	28.69	30.14	MS Mono [MF]

morphine sulfate pentahydrate 50 mg modified release capsule, 28

2840L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	41.17	31.60	Kapanol [YN]

morphine sulfate pentahydrate 60 mg modified release capsule, 14

8492Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	36.30	31.60	MS Mono [MF]

morphine sulfate pentahydrate 90 mg modified release capsule, 14

8493B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	39.95	31.60	MS Mono [MF]

morphine sulfate pentahydrate 10 mg modified release tablet, 28

1653B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	25.97	27.42	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

morphine sulfate pentahydrate 100 mg modified release tablet, 28

1656E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	62.15	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

morphine sulfate pentahydrate 15 mg modified release tablet, 28

8489T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	31.96	31.60	MS Contin [MF]

morphine sulfate pentahydrate 30 mg modified release tablet, 28

1654C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	36.32	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

morphine sulfate pentahydrate 5 mg modified release tablet, 28

8035X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	25.60	27.05	MS Contin [MF]

morphine sulfate pentahydrate 60 mg modified release tablet, 28

1655D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	49.54	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL

2122Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	31.92	31.60	[a] Ordine 2 [XT]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Chronic severe disabling pain

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

morphine sulfate pentahydrate 200 mg modified release tablet, 28

8453X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	121.43	31.60	MS Contin [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Morphini HCl Streuli or the brand RA-Morph (NZ) can be substituted for pharmaceutical benefits that have the brand Ordine 10 in case of a shortage.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL

14083F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	10	..	..	*566.44	31.60	[a] Morphini HCl Streuli [DZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

14194C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	154.95	31.60	[a] RA-Morph (NZ) [WZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

2124T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	35.81	31.60	[a] Ordine 10 [XT]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

oxycodone hydrochloride 10 mg capsule, 20

12074L DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	..	..	*23.28	24.73	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 10

12311Y DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	21.74	23.19	OxyNorm [MF]

oxycodone hydrochloride 5 mg tablet, 10

13234M DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	20.49	21.94	[a] Oxycodone Viatris [MQ]
		[B]1.00	21.49	21.94	[a] ENDONE [AF]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

oxycodone hydrochloride 10 mg capsule, 20

5197M DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.52	24.97	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 20

5191F DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	24.24	25.69	OxyNorm [MF]

oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

5190E DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	32.07	31.60	OxyNorm Liquid 1mg/mL [MF]

oxycodone hydrochloride 5 mg tablet, 20

5195K DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	21.74	23.19	[a] Mayne Pharma Oxycodone IR [YN] [a] Oxyndone [TX]	[a] Oxycodone Viatris [MQ]
		[B]2.00	23.74	23.19	[a] ENDONE [AF]	

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

oxycodone 30 mg suppository, 12

5194J DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	51.18	31.60	Proladone [FF]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

oxycodone hydrochloride 10 mg capsule, 20

12031F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	..	..	*23.28	24.73	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 10

12314D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	21.74	23.19	OxyNorm [MF]

oxycodone hydrochloride 5 mg tablet, 10

13233L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	20.49	21.94	[a] Oxycodone Viatris [MQ]
		[B]1.00	21.49	21.94	[a] ENDONE [AF]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone 30 mg suppository, 12

2481N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	51.18	31.60	Proladone [FF]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg capsule, 20

8501K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.52	24.97	OxyNorm [MF]

oxycodone hydrochloride 20 mg capsule, 20

8502L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.87	28.32	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 20

8464L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	24.24	25.69	OxyNorm [MF]

oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

8644Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	32.07	31.60	OxyNorm Liquid 1mg/mL [MF]

oxycodone hydrochloride 5 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2622B NP	1	..	..	21.74	23.19	[a] Mayne Pharma Oxycodone IR [YN] [a] Oxyndone [TX]	[a] Oxycodone Viatris [MQ]
			[B]2.00	23.74	23.19	[a] ENDONE [AF]	

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg modified release tablet, 28

8385H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	29.83	31.28	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 15 mg modified release tablet, 28

9399Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	38.07	31.60	OxyContin [MF]

oxycodone hydrochloride 20 mg modified release tablet, 28

8386J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	38.31	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 30 mg modified release tablet, 28

9400R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	51.65	31.60	OxyContin [MF]

oxycodone hydrochloride 40 mg modified release tablet, 28

8387K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	48.29	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 80 mg modified release tablet, 28

8388L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	67.10	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

▪ OXYCODONE + NALOXONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28

8934F

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	37.56	31.60	Targin 10/5mg [MF]

oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8935G NP	1	..	..	52.05	31.60	Targin 20/10mg [MF]

oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8936H NP	1	..	..	69.05	31.60	Targin 40/20mg [MF]

oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8000C NP	1	..	..	36.43	31.60	Targin 5/2.5mg [MF]

oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11102H NP	1	..	..	84.45	31.60	Targin 60/30 [MF]

oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11111T NP	1	..	..	87.94	31.60	Targin 80/40 [MF]

oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10776E NP	1	..	..	28.69	30.14	Targin 2.5/1.25 mg [MF]

oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10757E NP	1	..	..	41.91	31.60	Targin 15/7.5mg [MF]

oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10758F NP	1	..	..	58.20	31.60	Targin 30/15 mg [MF]

Phenylpiperidine derivatives

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
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Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 12 microgram/hour patch, 5

5265D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	24.00	25.45	[a] Denpax [AF]

fentanyl 12 microgram/hour patch, 5

5437E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	25.22	26.67	[a] Fenpatch 12 [RW]

fentanyl 12 microgram/hour patch, 5

8878G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	24.00	25.45	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 12 [JC]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 25 microgram/hour patch, 5

5277R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	25.41	26.86	[a] Denpax [AF]

fentanyl 25 microgram/hour patch, 5

5438F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	26.96	28.41	[a] Fenpatch 25 [RW]

fentanyl 25 microgram/hour patch, 5

8891Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	25.41	26.86	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 25 [JC]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 50 microgram/hour patch, 5

5278T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	30.92	31.60	[a] Denpax [AF]

fentanyl 50 microgram/hour patch, 5

5439G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	33.76	31.60	[a] Fenpatch 50 [RW]

fentanyl 50 microgram/hour patch, 5

8892B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	30.92	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 50 [JC]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 75 microgram/hour patch, 5

5279W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	35.39	31.60	[a] Denpax [AF]

fentanyl 75 microgram/hour patch, 5

5440H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	39.30	31.60	[a] Fenpatch 75 [RW]

fentanyl 75 microgram/hour patch, 5

8893C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	35.39	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 75 [JC]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**

- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 100 microgram/hour patch, 5

5280X

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	39.38	31.60	[a] Denpax [AF]

fentanyl 100 microgram/hour patch, 5

5441J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	44.01	31.60	[a] Fenpatch 100 [RW]

fentanyl 100 microgram/hour patch, 5

8894D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	39.38	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 100 [JC]

Diphenylpropylamine derivatives

▪ METHADONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note This treatment is not recommended for use in ambulant patients.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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[Your capital city]

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

methadone hydrochloride 10 mg tablet, 20

1609Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	24.13	25.58	Physeptone [AS]

▪ METHADONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note This treatment is not recommended for use in ambulant patients.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Note Pharmaceutical benefits that have the form methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules and pharmaceutical benefits that have the form methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10747

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10751

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14202L NP	1	..	..	54.27	31.60	Physeptone [AS]

Oripavine derivatives

▪ BUPRENORPHINE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

buprenorphine 10 microgram/hour patch, 2

8866P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	32.40	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 20 microgram/hour patch, 2

8867Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	39.76	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 5 microgram/hour patch, 2

8865N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	26.37	27.82	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 15 microgram/hour patch, 2

10770W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	36.08	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 25 microgram/hour patch, 2

10756D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	43.25	31.60	[a] Bupredermal [TX] [a] Norspan [MF]	[a] Buprenorphine Sandoz [SZ]

buprenorphine 30 microgram/hour patch, 2

10755C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	46.73	31.60	[a] Bupredermal [TX] [a] Norspan [MF]	[a] Buprenorphine Sandoz [SZ]

buprenorphine 40 microgram/hour patch, 2

10746N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	53.72	31.60	[a] Bupredermal [TX] [a] Norspan [MF]	[a] Buprenorphine Sandoz [SZ]

Opioids in combination with non-opioid analgesics

▪ PARACETAMOL + CODEINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

12066C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	0.5	..	..	*16.80	18.25	[a] APO- Paracetamol/Codeine 500/30 [TX] [a] Codalgin Forte [AF] [a] Comfarol Forte [SZ] [a] Prodeine Forte [AV]	[a] APX-Paracetamol/Codeine [TY] [a] Codapane Forte 500/30 [AL] [a] Paracetamol/Codeine GH 500/30 [GQ]
			[B]2.05	*18.85	18.25	[a] Panadeine Forte [SW]	

▪ PARACETAMOL + CODEINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

3316M (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.37	17.82	[a] APO- Paracetamol/Codeine 500/30 [TX] [a] Codalgin Forte [AF] [a] Comfarol Forte [SZ] [a] Prodeine Forte [AV]	[a] APX-Paracetamol/Codeine [TY] [a] Codapane Forte 500/30 [AL] [a] Paracetamol/Codeine GH 500/30 [GQ]
		[B]3.30	19.67	17.82	[a] Panadeine Forte [SW]	

▪ PARACETAMOL + CODEINE

Caution The risk of drug dependence is high.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

12022R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
0.5	..	..	*16.80	18.25	[a] APO- Paracetamol/Codeine 500/30 [TX] [a] Codalgin Forte [AF] [a] Comfarol Forte [SZ] [a] Prodeine Forte [AV]	[a] APX-Paracetamol/Codeine [TY] [a] Codapane Forte 500/30 [AL] [a] Paracetamol/Codeine GH 500/30 [GQ]
		[B]2.05	*18.85	18.25	[a] Panadeine Forte [SW]	

▪ PARACETAMOL + CODEINE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1215Y NP	1	..	..	16.37	17.82	[a] APO- Paracetamol/Codeine 500/30 [TX] [a] Codalgin Forte [AF] [a] Comfarol Forte [SZ] [a] Prodeine Forte [AV]	[a] APX-Paracetamol/Codeine [TY] [a] Codapane Forte 500/30 [AL] [a] Paracetamol/Codeine GH 500/30 [GQ]
			[B]3.30	19.67	17.82	[a] Panadeine Forte [SW]	

Other opioids

▪ TAPENTADOL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

tapentadol 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10094G NP	1	..	..	37.15	31.60	Palexia SR [CS]

tapentadol 150 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10100N NP	1	..	..	44.33	31.60	Palexia SR [CS]

tapentadol 200 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10091D NP	1	..	..	50.68	31.60	Palexia SR [CS]

tapentadol 250 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10092E NP	1	..	..	56.05	31.60	Palexia SR [CS]

tapentadol 50 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10096J NP	1	..	..	29.68	31.13	Palexia SR [CS]

▪ TRAMADOL

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

tramadol hydrochloride 50 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12024W DP	0.5	..	..	*16.80	18.25	[a] APO-Tramadol [TX] [a] Tramedo [AF]	[a] Tramadol Sandoz [SZ] [a] Zydol [RW]
			[B]1.40	*18.20	18.25	[a] Tramal [CS]	

▪ TRAMADOL

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

tramadol hydrochloride 50 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5232J DP	1	..	..	16.37	17.82	[a] APO-Tramadol [TX] [a] Tramedo [AF]	[a] Tramadol Sandoz [SZ] [a] Zydol [RW]
			[B]2.25	18.62	17.82	[a] Tramal [CS]	

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5231H DP	1	..	..	17.02	18.47	[a] Tramadol AN [JU] [a] Tramal 100 [CS]	[a] Tramadol Sandoz [SZ]

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5150C DP	‡1	..	..	19.80	21.25	Tramal [CS]

▪ TRAMADOL

Caution The risk of drug dependence is high.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

tramadol hydrochloride 50 mg capsule, 20

12008B

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
0.5	..	..	*16.80	18.25	[a] APO-Tramadol [TX]	[a] Tramadol Sandoz [SZ]
					[a] Tramedo [AF]	[a] Zydol [RW]
		[B]1.40	*18.20	18.25	[a] Tramal [CS]	

▪ TRAMADOL

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

tramadol hydrochloride 50 mg capsule, 20

8455B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.37	17.82	[a] APO-Tramadol [TX] [a] Tramedo [AF]	[a] Tramadol Sandoz [SZ] [a] Zydol [RW]
		[B]2.25	18.62	17.82	[a] Tramal [CS]	

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

8582Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.02	18.47	[a] Tramadol AN [JU] [a] Tramal 100 [CS]	[a] Tramadol Sandoz [SZ]

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

8843K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	19.80	21.25	Tramal [CS]

▪ TRAMADOL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

tramadol hydrochloride 100 mg modified release tablet, 20

8523N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.61	18.06	[a] APO-Tramadol SR [TX] [a] Tramadol SR generichealth [GQ] [a] Zydol SR 100 [RW]	[a] Tramadol Sandoz SR [SZ] [a] Tramedo SR [AL]
		[B]4.29	20.90	18.06	[a] Tramal SR 100 [CS]	

tramadol hydrochloride 150 mg modified release tablet, 20

8524P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.37	18.82	[a] APO-Tramadol SR [TX] [a] Tramadol SR generichealth [GQ] [a] Zydol SR 150 [RW]	[a] Tramadol Sandoz SR [SZ] [a] Tramedo SR [AL]
			[B]5.23	22.60	18.82	[a] Tramal SR 150 [CS]	

tramadol hydrochloride 200 mg modified release tablet, 20

8525Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.53	18.98	[a] APO-Tramadol SR [TX] [a] Tramadol SR generichealth [GQ] [a] Zydol SR 200 [RW]	[a] Tramadol Sandoz SR [SZ] [a] Tramedo SR [AL]
			[B]5.95	23.48	18.98	[a] Tramal SR 200 [CS]	

tramadol hydrochloride 50 mg modified release tablet, 20

2527B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	17.30	18.75	Tramal SR 50 [CS]

OTHER ANALGESICS AND ANTIPYRETICS

Anilides

▪ PARACETAMOL

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

paracetamol 24 mg/mL oral liquid, 100 mL

1747Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	16.26	17.71	Panamax [SW]

paracetamol 48 mg/mL oral liquid, 200 mL

1770E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	17.31	18.76	Panamax 240 Elixir [SW]

paracetamol 500 mg tablet, 100

1746X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.13	16.58	[a] APO-Paracetamol [TX] [a] Panamax [SW] [a] Paracetamol Sandoz Pharma [QS] [a] Parapane [AF] [a] Wagner Health Paracetamol [BG]	[a] Febridol [XT] [a] Paracetamol (Sandoz) [SZ] [a] Paralgin [OW] [a] PHARMACY CARE PARACETAMOL [SI]

▪ PARACETAMOL

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

paracetamol 24 mg/mL oral liquid, 100 mL

3348F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	16.26	17.71	Panamax [SW]

paracetamol 48 mg/mL oral liquid, 200 mL

3349G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	17.31	18.76	Panamax 240 Elixir [SW]

paracetamol 500 mg tablet, 100

5196L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.13	16.58	[a] APO-Paracetamol [TX] [a] Panamax [SW] [a] Paracetamol Sandoz Pharma [QS] [a] Parapane [AF] [a] Wagner Health Paracetamol [BG]	[a] Febridol [XT] [a] Paracetamol (Sandoz) [SZ] [a] Paralgin [OW] [a] PHARMACY CARE PARACETAMOL [SI]

▪ PARACETAMOL

Restricted benefit

Chronic arthropathies

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 500 mg tablet, 100

5224Y (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*18.48	19.93	[a] APO-Paracetamol [TX]	[a] Febridol [XT]
					[a] Panamax [SW]	[a] Paracetamol (Sandoz) [SZ]
					[a] Paracetamol Sandoz Pharma [QS]	[a] Paralgin [OW]
					[a] Parapane [AF]	[a] PHARMACY CARE PARACETAMOL [SI]
					[a] Wagner Health Paracetamol [BG]	

▪ PARACETAMOL

Restricted benefit

Chronic arthropathies

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 500 mg tablet, 100

8784H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	4	..	*18.48	19.93	[a] APO-Paracetamol [TX]	[a] Febridol [XT]
					[a] Panamax [SW]	[a] Paracetamol (Sandoz) [SZ]
					[a] Paracetamol Sandoz Pharma [QS]	[a] Paralgin [OW]
					[a] Parapane [AF]	[a] PHARMACY CARE PARACETAMOL [SI]
					[a] Wagner Health Paracetamol [BG]	

▪ PARACETAMOL

Note Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

Restricted benefit

Persistent pain

Clinical criteria:

- The condition must be associated with osteoarthritis.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 665 mg modified release tablet, 96

8814X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	22.44	[a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX]	[a] Osteomol 665 Paracetamol [CR]
					[a] Parapane OSTEO [AF]	

paracetamol 665 mg modified release tablet, 192

10797G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.99	22.44	[a] Osteomol 665 Paracetamol [CR]	[a] Parapane OSTEO [AF]

Gabapentinoids

▪ PREGABALIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4172

Neuropathic pain

Clinical criteria:

- The condition must be refractory to treatment with other drugs.

pregabalin 150 mg capsule, 56

2355Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.35	24.80	[a] APO-Pregabalin [TX]	[a] Blooms The Chemist Pregabalin [IB]
					[a] BTC Pregabalin [BG]	[a] Cipla Pregabalin [LR]
					[a] Lyrica [UJ]	[a] Lyzalon [AF]
					[a] Neuroccord [CR]	[a] NOUMED PREGABALIN [VO]

						[a] Prebalin [RF]	[a] PREGABALIN-DRLA [RZ]
						[a] Pregabalin Lupin [HQ]	[a] Pregabalin Sandoz [SZ]

pregabalin 25 mg capsule, 56

2348N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.60	19.05	[a] APO-Pregabalin [TX]	[a] Blooms The Chemist Pregabalin [IB]
						[a] BTC Pregabalin [BG]	[a] Cipla Pregabalin [LR]
						[a] Lyrica [UJ]	[a] Lyzalon [AF]
						[a] Neuroccord [CR]	[a] NOUMED PREGABALIN [VO]
						[a] Prebalin [RF]	[a] PREGABALIN-DRLA [RZ]
						[a] Pregabalin Lupin [HQ]	[a] Pregabalin Sandoz [SZ]

pregabalin 300 mg capsule, 56

2363J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.21	29.66	[a] APO-Pregabalin [TX]	[a] Blooms The Chemist Pregabalin [IB]
						[a] BTC Pregabalin [BG]	[a] Cipla Pregabalin [LR]
						[a] Lyrica [UJ]	[a] Lyzalon [AF]
						[a] Neuroccord [CR]	[a] NOUMED PREGABALIN [VO]
						[a] Prebalin [RF]	[a] PREGABALIN-DRLA [RZ]
						[a] Pregabalin Lupin [HQ]	[a] Pregabalin Sandoz [SZ]

pregabalin 75 mg capsule, 56

2335X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.90	21.35	[a] APO-Pregabalin [TX]	[a] Blooms The Chemist Pregabalin [IB]
						[a] BTC Pregabalin [BG]	[a] Cipla Pregabalin [LR]
						[a] Lyrica [UJ]	[a] Lyzalon [AF]
						[a] Neuroccord [CR]	[a] NOUMED PREGABALIN [VO]
						[a] Prebalin [RF]	[a] PREGABALIN-DRLA [RZ]
						[a] Pregabalin Lupin [HQ]	[a] Pregabalin Sandoz [SZ]

ANTIMIGRAINE PREPARATIONS

Selective serotonin (5HT1) agonists

▪ ELETRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

eletriptan 40 mg tablet, 4

5290K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	27.09	28.54	Relpax [UJ]

eletriptan 80 mg tablet, 4

5291L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	27.09	28.54	Relpax [UJ]

▪ NARATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

naratriptan 2.5 mg tablet, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8298R NP	2	5	[S]1.54	*25.71	25.62	Naramig [AS]

▪ NARATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

naratriptan 2.5 mg tablet, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9734H NP	2	5	..	*25.71	27.16	Naramig [AS]

▪ RIZATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

rizatriptan 10 mg wafer, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9313E NP	2	5	[B]2.74	*24.81	23.52	[a] Rizatriptan Wafers-10mg [AF]
			[B]3.92	*25.99	23.52	[a] Maxalt [AL]

rizatriptan 10 mg orally disintegrating tablet, 2

10551H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	[a] APO-Rizatriptan [TX]	[a] RIXALT [RF]
						[a] Rizatriptan ODT APOTEX [GX]	[a] Rizatriptan ODT GH [GQ]

▪ SUMATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4

10694W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	[B]4.19	23.89	21.15	[a] Imigran FDT [AS]

sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation

8341B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	25.30	26.75	Imigran [AS]

sumatriptan 50 mg tablet, 2

8144P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.71	21.16	[a] APO-Sumatriptan [TX]	[a] Iptam [AL]
						[a] Sumagraine Migraine Relief [GQ]	[a] Sumatran [OW]
			[B]4.18	*23.89	21.16	[a] Imigran [LN]	[a] IMIGRAN MIGRAINE [AS]

sumatriptan 50 mg tablet, 4

1849H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.70	21.15	[a] APO-Sumatriptan [TX]	[a] Iptam [AL]
						[a] Pharmacor Sumatriptan 50 [CR]	[a] Sumatran [OW]
						[a] Sumatriptan generichealth [GQ]	[a] Sumatriptan Sandoz [SZ]
			[B]4.19	23.89	21.15	[a] Imigran [LN]	

▪ ZOLMITRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

zolmitriptan 2.5 mg tablet, 2

8266C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.35	26.80	[a] APO-Zolmitriptan [TX]	[a] Zoltrip [RW]
			[B]4.50	*29.85	26.80	[a] Zomig [AP]	

Calcitonin gene-related peptide (CGRP) antagonists

▪ EPTINEZUMAB

Note Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14189

Chronic migraine

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

Clinical criteria:

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

Population criteria:

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

eptinezumab 100 mg/mL injection, 1 mL vial

13342F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1448.78	31.60	Vyepti [LU]

▪ EPTINEZUMAB

Note Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12029

Chronic migraine

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine days per month documented in their medical records.

eptinezumab 100 mg/mL injection, 1 mL vial

13352R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1448.78	31.60	Vyepti [LU]

▪ FREMANEZUMAB

Note Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14563

Treatment-resistant migraine

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine headache days per month documented in their medical records.

fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device

13129B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	560.39	31.60	[a] Ajovy [TB]

fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe

12603H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	560.39	31.60	[a] Ajovy [TB]

▪ FREMANEZUMAB

Note Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14472

Treatment-resistant migraine

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

Clinical criteria:

- Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

Population criteria:

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine headache days per month documented in their medical records.

fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device

13115G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.39	31.60	[a] Ajovy [TB]

fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe

12611R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	560.39	31.60	[a] Ajovy [TB]

Other antimigraine preparations

▪ GALCANEZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12029

Chronic migraine

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine days per month documented in their medical records.

galcanezumab 120 mg/mL injection, 1 mL pen device

12469G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	523.03	31.60	Emgality [LY]

▪ GALCANEZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12064

Chronic migraine

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

Clinical criteria:

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

galcanezumab 120 mg/mL injection, 1 mL pen device

12478R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*1037.61	31.60	Emgality [LY]

▪ PIZOTIFEN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

pizotifen 500 microgram tablet, 100

3074T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	25.07	26.52	Sandomigran 0.5 [AE]

▪ PIZOTIFEN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pizotifen 500 microgram tablet, 100

13866T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*36.69	31.60	Sandomigran 0.5 [AE]

▪ ANTIEPILEPTICS

ANTIEPILEPTICS

Barbiturates and derivatives

▪ PHENOBARBITAL

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Epilepsy

phenobarbital 30 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1850J NP	1	4	..	19.07	20.52	Phenobarb [RW]

phenobarbital 200 mg (equivalent to phenobarbital sodium 219 mg)/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2138M NP	1	..	..	36.49	31.60	Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd) [AS]

▪ PRIMIDONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

primidone 250 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1939C NP	1	2	..	70.36	31.60	Mysoline [LM]

Hydantoin derivatives

▪ PHENYTOIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

phenytoin 30 mg/5 mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2692Q NP	‡1	3	..	26.58	28.03	Dilantin [UJ]

phenytoin 50 mg chewable tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1249R NP	1	2	..	65.64	31.60	Dilantin Infatabs [UJ]

phenytoin sodium 100 mg capsule, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1874P NP	1	2	..	33.78	31.60	Dilantin Sodium [UJ]

phenytoin sodium 30 mg capsule, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1873N NP	1	2	..	53.03	31.60	Dilantin Sodium [UJ]

▪ PHENYTOIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

phenytoin 30 mg/5 mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13841L NP	‡2	3	..	*39.71	31.60	Dilantin [UJ]

phenytoin 50 mg chewable tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13894G NP	2	2	..	*118.03	31.60	Dilantin Infatabs [UJ]

phenytoin sodium 100 mg capsule, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13972J NP	2	2	..	*54.11	31.60	Dilantin Sodium [UJ]

phenytoin sodium 30 mg capsule, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14015P NP	2	2	..	*92.61	31.60	Dilantin Sodium [UJ]

Succinimide derivatives

▪ ETHOSUXIMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

ethosuximide 250 mg/5 mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1414K NP	‡1	5	..	74.05	31.60	Zarontin [IX]

▪ ETHOSUXIMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 100, and pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 56 are equivalent for the purposes of substitution.

ethosuximide 250 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13127X NP	3.57	2	..	*306.67	31.60	[a] Ethosuximide Essential Generics (UK) [IX]

ethosuximide 250 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11703Y NP	2	2	..	*296.33	31.60	[a] Zarontin [IX]

▪ ETHOSUXIMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

ethosuximide 250 mg/5 mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14014N NP	‡2	5	..	*135.69	31.60	Zarontin [IX]

Benzodiazepine derivatives

▪ CLONAZEPAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Epilepsy

clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1807D NP	1	..	..	24.03	25.48	Rivotril [PB]

▪ CLONAZEPAM

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Epilepsy
Clinical criteria:
- The condition must be neurologically proven.

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1808E NP	2	..	..	*20.99	22.44	Rivotril [PB]

clonazepam 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1806C NP	2	2	..	*32.45	31.60	Paxam 2 [AF]

▪ CLONAZEPAM

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Epilepsy

Clinical criteria:

- The condition must be neurologically proven.

clonazepam 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1805B NP	2	2	..	*27.01	28.46	[a] Paxam 0.5 [AF]

clonazepam 500 microgram tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11559J NP	4	2	[B]3.68	*30.71	28.48	[a] Rivotril [PB]

▪ NITRAZEPAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2732T NP	2	5	..	*18.89	20.34	[a] Alodorm [AF]	[a] Mogadon [IL]

Carboxamide derivatives

▪ CARBAMAZEPINE

carbamazepine 100 mg/5 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5041H DP	‡1	..	..	26.44	27.89	Tegretol Liquid [NV]

carbamazepine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5039F DP	2	..	..	*23.89	25.34	[a] Carbamazepine Sandoz [NM]
			[B]2.66	*26.55	25.34	[a] Tegretol 100 [NV]

carbamazepine 200 mg tablet, 100

1724R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*30.89	31.60	[a] Carbamazepine Sandoz [NM]
		[B]2.62	*33.51	31.60	[a] Tegretol 200 [NV]

DP

carbamazepine 200 mg modified release tablet, 200

5038E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	31.24	31.60	Tegretol CR 200 [NV]

DP

carbamazepine 400 mg modified release tablet, 200

5037D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	47.24	31.60	Tegretol CR 400 [NV]

DP

▪ CARBAMAZEPINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

carbamazepine 100 mg/5 mL oral liquid, 300 mL

2427R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	26.44	27.89	Tegretol Liquid [NV]

NP

carbamazepine 100 mg tablet, 100

2422L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*23.89	25.34	[a] Carbamazepine Sandoz [NM]
		[B]2.66	*26.55	25.34	[a] Tegretol 100 [NV]

NP

carbamazepine 200 mg tablet, 100

1706T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*30.89	31.60	[a] Carbamazepine Sandoz [NM]
		[B]2.62	*33.51	31.60	[a] Tegretol 200 [NV]

NP

carbamazepine 200 mg modified release tablet, 200

2426Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	31.24	31.60	Tegretol CR 200 [NV]

NP

carbamazepine 400 mg modified release tablet, 200

2431Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	47.24	31.60	Tegretol CR 400 [NV]

NP

▪ CARBAMAZEPINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

carbamazepine 100 mg/5 mL oral liquid, 300 mL

14051M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*39.43	31.60	Tegretol Liquid [NV]

NP

carbamazepine 200 mg modified release tablet, 200

14050L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*49.03	31.60	Tegretol CR 200 [NV]

NP

carbamazepine 400 mg modified release tablet, 200

13918M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*81.03	31.60	Tegretol CR 400 [NV]

NP

▪ OXCARBAZEPINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5183

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 60 mg/mL oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8588B NP	2	5	..	*99.91	31.60	Trileptal [NV]

oxcarbazepine 150 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8584T NP	1	5	..	56.68	31.60	Trileptal [NV]

oxcarbazepine 300 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8585W NP	1	5	..	84.79	31.60	Trileptal [NV]

oxcarbazepine 600 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8586X NP	1	5	..	133.60	31.60	Trileptal [NV]

▪ OXCARBAZEPINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14932

Seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 60 mg/mL oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13936L NP	4	5	..	*189.99	31.60	Trileptal [NV]

oxcarbazepine 300 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14033N NP	2	5	..	*158.25	31.60	Trileptal [NV]

oxcarbazepine 600 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13935K NP	2	5	..	*258.73	31.60	Trileptal [NV]

Fatty acid derivatives

▪ TIAGABINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4928

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

tiagabine 10 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8222R NP	2	5	..	*111.25	31.60	Gabitril [TB]

tiagabine 15 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8223T NP	2	5	..	*156.13	31.60	Gabitril [TB]

tiagabine 5 mg tablet, 50

8221Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*62.35	31.60	Gabitril [TB]

▪ TIAGABINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14883

Partial epileptic seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

tiagabine 10 mg tablet, 50

13947C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*213.79	31.60	Gabitril [TB]

tiagabine 15 mg tablet, 50

13893F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*303.79	31.60	Gabitril [TB]

tiagabine 5 mg tablet, 50

13892E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*111.23	31.60	Gabitril [TB]

▪ VALPROATE

Caution There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

valproate sodium 100 mg tablet, 100

2294R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*35.71	31.60	Epilim [SW]

valproate sodium 200 mg enteric tablet, 100

2289L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*22.07	23.52	[a] APO-Sodium Valproate [TX]	[a] Sodium Valproate Sandoz [SZ]
						[a] Valprease 200 [RW]	[a] Valproate Winthrop EC 200 [WA]
						[a] Valpro EC 200 [AF]	
			[B]1.46	*23.53	23.52	[a] Epilim EC [SW]	

valproate sodium 500 mg enteric tablet, 100

2290M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*29.53	30.98	[a] APO-Sodium Valproate [TX]	[a] Sodium Valproate Sandoz [SZ]
						[a] Valprease 500 [RW]	[a] Valproate Winthrop EC 500 [WA]
						[a] Valpro EC 500 [AF]	
			[B]1.38	*30.91	30.98	[a] Epilim EC [SW]	

valproate sodium 200 mg/5 mL oral liquid, 300 mL

2293Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*42.29	31.60	Epilim Liquid [SW]

valproate sodium 200 mg/5 mL oral liquid, 300 mL

2295T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*42.29	31.60	Epilim Syrup [SW]

▪ VALPROATE

Caution There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

valproate sodium 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13840K NP	4	2	..	*57.95	31.60	Epilim [SW]

valproate sodium 200 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14017R NP	4	2	..	*30.67	31.60	[a] APO-Sodium Valproate [TX] [a] Valprease 200 [RW] [a] Valpro EC 200 [AF]	[a] Sodium Valproate Sandoz [SZ] [a] Valproate Winthrop EC 200 [WA]
			[B]2.92	*33.59	31.60	[a] Epilim EC [SW]	

valproate sodium 500 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13917L NP	4	2	..	*45.59	31.60	[a] APO-Sodium Valproate [TX] [a] Valprease 500 [RW] [a] Valpro EC 500 [AF]	[a] Sodium Valproate Sandoz [SZ] [a] Valproate Winthrop EC 500 [WA]
			[B]2.76	*48.35	31.60	[a] Epilim EC [SW]	

valproate sodium 200 mg/5 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13950F NP	4	2	..	*71.11	31.60	Epilim Syrup [SW]

valproate sodium 200 mg/5 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13973K NP	4	2	..	*71.11	31.60	Epilim Liquid [SW]

▪ VIGABATRIN

Caution Visual field defects have been reported with this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4929
Epileptic seizures
Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

vigabatrin 500 mg powder for oral liquid, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2668K NP	1	5	..	61.21	31.60	Sabril [SW]

vigabatrin 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2667J NP	1	5	..	87.22	31.60	Sabril [SW]

▪ VIGABATRIN

Caution Visual field defects have been reported with this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
14903
Epileptic seizures
Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

vigabatrin 500 mg powder for oral liquid, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13974L NP	2	5	..	*108.97	31.60	Sabril [SW]

vigabatrin 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13919N NP	2	5	..	*163.35	31.60	Sabril [SW]

Other antiepileptics

▪ BRIVARACETAM

Authority required (STREAMLINED)

10210

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

brivaracetam 25 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11328F	1	5	..	157.29	31.60	Briviact [UC]

brivaracetam 50 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11334M	1	5	..	157.29	31.60	Briviact [UC]

brivaracetam 75 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11356Q	1	5	..	157.29	31.60	Briviact [UC]

brivaracetam 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11339T	1	5	..	157.29	31.60	Briviact [UC]

▪ BRIVARACETAM

Authority required (STREAMLINED)

10251

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

brivaracetam 10 mg/mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11349H	1	5	..	194.50	31.60	Briviact [UC]

▪ BRIVARACETAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

10208

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with levetiracetam.

brivaracetam 25 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11327E NP	1	5	..	157.29	31.60	Briviact [UC]

brivaracetam 50 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11338R NP	1	5	..	157.29	31.60	Briviact [UC]

brivaracetam 75 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11350J NP	1	5	..	157.29	31.60	Briviact [UC]

brivaracetam 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11357R NP	1	5	..	157.29	31.60	Briviact [UC]

▪ BRIVARACETAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

10330

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam.

brivaracetam 10 mg/mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11358T NP	1	5	..	194.50	31.60	Briviact [UC]

▪ CANNABIDIOL

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe myoclonic epilepsy in infancy (Dravet syndrome)

Clinical criteria:

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

cannabidiol 100 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12467E	1	5	..	1535.31	31.60	Epidyolex [EU]

▪ CANNABIDIOL

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Seizures of the Lennox-Gastaut syndrome

Clinical criteria:

- Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible), **AND**
- Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures, **AND**
- Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

cannabidiol 100 mg/mL oral liquid, 100 mL

13277T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1535.31	31.60	Epidyolex [EU]

▪ GABAPENTIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4928

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

gabapentin 100 mg capsule, 100

8505P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.63	19.08	[a] APX-Gabapentin [GX] [a] GAPENTIN [RF] [a] Nupentin 100 [AF]	[a] Gabacor [CR] [a] Neurontin [UJ]

gabapentin 300 mg capsule, 100

1834M

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	24.95	26.40	[a] APX-Gabapentin [GX] [a] Gabapentin generichealth [HQ] [a] GAPENTIN [RF] [a] Nupentin 300 [AF]	[a] Gabacor [CR] [a] Gabapentin Sandoz [SZ] [a] Neurontin [UJ]

gabapentin 400 mg capsule, 100

1835N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	29.13	30.58	[a] APX-Gabapentin [GX] [a] Gabapentin generichealth [HQ] [a] GAPENTIN [RF] [a] Nupentin 400 [AF]	[a] Gabacor [CR] [a] Gabapentin Sandoz [SZ] [a] Neurontin [UJ]

gabapentin 600 mg tablet, 100

8559L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	38.32	31.60	[a] Gabapentin APOTEX [TY] [a] Neurontin [UJ]	[a] GAPENTIN [RF] [a] Pharmacor Gabapentin 600 [CR]

gabapentin 800 mg tablet, 100

8389M

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	46.61	31.60	[a] Gabapentin APOTEX [TY] [a] Neurontin [UJ]	[a] GAPENTIN [RF] [a] Pharmacor Gabapentin 800 [CR]

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

8813

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must be for dose titration purposes.

lacosamide 50 mg tablet, 14

9333F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	24.28	25.73	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

lacosamide 100 mg tablet, 14

9334G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	35.10	31.60	[a] Lacoress [LR] [a] Vimcosa [CR]	[a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

lacosamide 150 mg tablet, 14

9336J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	45.91	31.60	[a] Lacoress [LR] [a] Vimpat [UC]	[a] Vimcosa [CR]

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14857

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 100 mg tablet, 56

13867W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*190.27	31.60	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

lacosamide 50 mg tablet, 14

14011K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8	5	..	*100.03	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

8815

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 50 mg tablet, 14

10293R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*56.75	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

NP

▪ LACOSAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12225

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Dose titration at the start of therapy, during therapy or to gradually cease treatment

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced, **AND**
- The treatment must be for dose titration purposes.

lacosamide 100 mg tablet, 14

12633X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	35.10	31.60	[a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Vimcosa [CR]

lacosamide 150 mg tablet, 14

12649R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	45.91	31.60	[a] Vimcosa [CR]	[a] Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:

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Authority required (STREAMLINED)

8770

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Authority required (STREAMLINED)

8815

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 100 mg tablet, 56

9335H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	100.04	31.60	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

NP

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

14857
Intractable partial epileptic seizures
Treatment Phase: Continuing treatment
Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14053P NP	2	5	..	*281.05	31.60	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

lacosamide 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13951G NP	2	5	..	*371.95	31.60	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

lacosamide 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14048J NP	‡12	5	..	*708.99	31.60	Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

15070
Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.

lacosamide 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12628P NP	‡2	5	..	*125.23	31.60	Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

15089
Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.

lacosamide 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14013M NP	‡4	5	..	*241.99	31.60	Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

8770

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Authority required (STREAMLINED)

8815

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9337K NP	1	5	..	144.75	31.60	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

lacosamide 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9338L NP	1	5	..	190.20	31.60	[a] Lacoress [LR] [a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]

lacosamide 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11694L NP	‡6	5	..	*358.77	31.60	Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing**.**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

15089

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a neurologist; OR

- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.

lacosamide 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13839J NP	2	5	..	*190.27	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

lacosamide 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13838H NP	2	5	..	*281.05	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

lacosamide 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13949E NP	2	5	..	*371.95	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

lacosamide 50 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14049K NP	8	5	..	*100.03	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing**.**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

15070

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.

lacosamide 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12634Y NP	1	5	..	100.04	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

lacosamide 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12627N NP	1	5	..	144.75	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ] [a] Vimcosa [CR]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ] [a] Vimpat [UC]

lacosamide 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12658F NP	1	5	..	190.20	31.60	[a] Lacosam [AF] [a] Lacosamide Lupin [GQ]	[a] Lacosamide ARX [XT] [a] Lacosamide Sandoz [SZ]

						[a] Vimcosa [CR]	[a] Vimpat [UC]

lacosamide 50 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12626M							
NP	4	5	..	*56.75	31.60	[a] Lacosam [AF]	[a] Lacosamide ARX [XT]
						[a] Lacosamide Lupin [GQ]	[a] Lacosamide Sandoz [SZ]
						[a] Vimcosa [CR]	[a] Vimpat [UC]

▪ LAMOTRIGINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

11081

Epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential.

lamotrigine 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2850B							
NP	1	5	..	23.28	24.73	[a] APX-Lamotrigine [TY]	[a] LAMITAN [RF]
						[a] Lamotrigine GH [GQ]	[a] Logem [AL]
						[a] NOUMED LAMOTRIGINE [VO]	[a] Reedos 100 [ZS]
						[a] Sandoz Lamotrigine [HX]	
			[B]3.45	26.73	24.73	[a] Lamictal [AS]	

lamotrigine 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2851C							
NP	1	5	..	29.96	31.41	[a] APX-Lamotrigine [TY]	[a] LAMITAN [RF]
						[a] Lamotrigine GH [GQ]	[a] Logem [AL]
						[a] NOUMED LAMOTRIGINE [VO]	[a] Reedos 200 [ZS]
						[a] Sandoz Lamotrigine [HX]	
			[B]3.46	33.42	31.41	[a] Lamictal [AS]	

lamotrigine 25 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2848X							
NP	1	5	..	17.76	19.21	[a] APX-Lamotrigine [TY]	[a] LAMITAN [RF]
						[a] Lamotrigine GH [GQ]	[a] Logem [AL]
						[a] NOUMED LAMOTRIGINE [VO]	[a] Reedos 25 [ZS]
						[a] Sandoz Lamotrigine [HX]	
			[B]4.28	22.04	19.21	[a] Lamictal [AS]	

lamotrigine 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8063J						
NP	1	5	..	19.78	21.23	Lamictal [AS]

lamotrigine 50 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2849Y							
NP	1	5	..	19.35	20.80	[a] APX-Lamotrigine [TY]	[a] LAMITAN [RF]
						[a] Lamotrigine GH [GQ]	[a] Logem [AL]
						[a] NOUMED LAMOTRIGINE [VO]	[a] Reedos 50 [ZS]
						[a] Sandoz Lamotrigine [HX]	
			[B]3.44	22.79	20.80	[a] Lamictal [AS]	

▪ LAMOTRIGINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14855

Epileptic seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential.

lamotrigine 100 mg tablet, 56

14052N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*33.11	31.60	[a] APX-Lamotrigine [TY] [a] Lamotrigine GH [GQ] [a] NOUMED LAMOTRIGINE [VO] [a] Sandoz Lamotrigine [HX]	[a] LAMITAN [RF] [a] Logem [AL] [a] Reedos 100 [ZS]
			[B]6.90	*40.01	31.60	[a] Lamictal [AS]	

lamotrigine 200 mg tablet, 56

13843N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*46.47	31.60	[a] APX-Lamotrigine [TY] [a] Lamotrigine GH [GQ] [a] NOUMED LAMOTRIGINE [VO] [a] Sandoz Lamotrigine [HX]	[a] LAMITAN [RF] [a] Logem [AL] [a] Reedos 200 [ZS]
			[B]6.92	*53.39	31.60	[a] Lamictal [AS]	

lamotrigine 25 mg tablet, 56

13842M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	[a] APX-Lamotrigine [TY] [a] Lamotrigine GH [GQ] [a] NOUMED LAMOTRIGINE [VO] [a] Sandoz Lamotrigine [HX]	[a] LAMITAN [RF] [a] Logem [AL] [a] Reedos 25 [ZS]
			[B]8.56	*30.63	23.52	[a] Lamictal [AS]	

lamotrigine 5 mg tablet, 56

14047H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*26.11	27.56	Lamictal [AS]

lamotrigine 50 mg tablet, 56

13975M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.25	26.70	[a] APX-Lamotrigine [TY] [a] Lamotrigine GH [GQ] [a] NOUMED LAMOTRIGINE [VO] [a] Sandoz Lamotrigine [HX]	[a] LAMITAN [RF] [a] Logem [AL] [a] Reedos 50 [ZS]
			[B]6.88	*32.13	26.70	[a] Lamictal [AS]	

▪ LEVETIRACETAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

11116

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 1 g tablet, 60

8656N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.18	31.60	[a] APO-Levetiracetam [TX] [a] Kevtam 1000 [AF] [a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ] [a] Levi 1000 [RW]	[a] Keppra [UC] [a] Levactam [ZS] [a] Levetiracetam Mylan [AL] [a] Levetiracetam Viatris [MQ] [a] NOUMED LEVETIRACETAM [VO]

levetiracetam 250 mg tablet, 60

8654L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.08	24.53	[a] APO-Levetiracetam [TX] [a] Kevtam 250 [AF] [a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ]	[a] Keppra [UC] [a] Levactam [ZS] [a] Levetiracetam Mylan [AL] [a] Levetiracetam Viatris [MQ]

						[a] Levi 250 [RW]	[a] NOUMED LEVETIRACETAM [VO]

levetiracetam 500 mg tablet, 60

8655M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.49	30.94	[a] APO-Levetiracetam [TX] [a] Kevtam 500 [AF] [a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ] [a] NOUMED LEVETIRACETAM [VO]	[a] Keppra [UC] [a] Levactam [ZS] [a] Levetiracetam Mylan [AL] [a] Levi 500 [RW]

▪ LEVETIRACETAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

11077

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 100 mg/mL oral liquid, 300 mL

9169N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	75.82	31.60	[a] APO-Levetiracetam [TX] [a] Kerron [ZS] [a] Levetiracetam GH [GQ]	[a] Keppra [UC] [a] Levetiracetam-AFT [AE]

▪ LEVETIRACETAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14964

Partial epileptic seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 1 g tablet, 60

13937M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*66.91	31.60	[a] APO-Levetiracetam [TX] [a] Kevtam 1000 [AF] [a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ] [a] Levi 1000 [RW]	[a] Keppra [UC] [a] Levactam [ZS] [a] Levetiracetam Mylan [AL] [a] Levetiracetam Viatris [MQ] [a] NOUMED LEVETIRACETAM [VO]

levetiracetam 250 mg tablet, 60

13992K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*32.71	31.60	[a] APO-Levetiracetam [TX] [a] Kevtam 250 [AF] [a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ] [a] Levi 250 [RW]	[a] Keppra [UC] [a] Levactam [ZS] [a] Levetiracetam Mylan [AL] [a] Levetiracetam Viatris [MQ] [a] NOUMED LEVETIRACETAM [VO]

levetiracetam 500 mg tablet, 60

14034P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*45.53	31.60	[a] APO-Levetiracetam [TX] [a] Kevtam 500 [AF] [a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ]	[a] Keppra [UC] [a] Levactam [ZS] [a] Levetiracetam Mylan [AL] [a] Levi 500 [RW]

[a] NOUMED LEVETIRACETAM [VO]

▪ LEVETIRACETAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14988

Partial epileptic seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 100 mg/mL oral liquid, 300 mL

13993L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡2	5	..	*139.41	31.60	[a] APO-Levetiracetam [TX] [a] Kerron [ZS] [a] Levetiracetam GH [GQ]	[a] Keppra [UC] [a] Levetiracetam-AFT [AE]

▪ PERAMPANEL

Authority required (STREAMLINED)

4656

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Treatment criteria:

- Must be treated by a neurologist.

perampanel 2 mg tablet, 7

10157N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*48.61	31.60	Fycompa [EI]

▪ PERAMPANEL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug.

perampanel 6 mg tablet, 28

10163X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	229.86	31.60	Fycompa [EI]

perampanel 8 mg tablet, 28

10160R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	303.63	31.60	Fycompa [EI]

perampanel 10 mg tablet, 28

10151G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	303.63	31.60	Fycompa [EI]

perampanel 12 mg tablet, 28

10159Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	303.63	31.60	Fycompa [EI]

perampanel 4 mg tablet, 28

10162W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	156.06	31.60	Fycompa [EI]

NP

▪ PERAMPANEL

Note No applications for increased maximum quantities will be authorised.

Authority required (STREAMLINED)

7815

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug, **AND**
- The treatment must be for dose titration purposes.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 2 mg tablet, 7

11436X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*48.61	31.60	Fycompa [EI]

▪ PERAMPANEL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14852

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug.

perampanel 6 mg tablet, 28

14010J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*451.27	31.60	Fycompa [EI]

NP

perampanel 8 mg tablet, 28

13970G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*598.79	31.60	Fycompa [EI]

NP

perampanel 10 mg tablet, 28

13914H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*598.79	31.60	Fycompa [EI]

NP

perampanel 12 mg tablet, 28

13865R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*598.79	31.60	Fycompa [EI]

NP

perampanel 4 mg tablet, 28

13948D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*303.65	31.60	Fycompa [EI]

NP

▪ PERAMPANEL

Note No applications for increased maximum quantities will be authorised.

Note Special Pricing Arrangements apply.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7789

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 6 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11407J NP	1	2	..	229.86	31.60	Fycompa [EI]

perampanel 8 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11429M NP	1	5	..	303.63	31.60	Fycompa [EI]

perampanel 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11428L NP	1	5	..	303.63	31.60	Fycompa [EI]

perampanel 12 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11409L NP	1	5	..	303.63	31.60	Fycompa [EI]

perampanel 4 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11418Y NP	1	2	..	156.06	31.60	Fycompa [EI]

▪ PERAMPANEL

Note No increase in the maximum quantity or number of units may be authorised.

Note Special Pricing Arrangements apply.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14847

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 6 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14046G NP	2	5	..	*451.27	31.60	Fycompa [EI]

perampanel 4 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13864Q NP	2	5	..	*303.65	31.60	Fycompa [EI]

▪ PERAMPANEL

Note No applications for increased maximum quantities will be authorised.

Note Special Pricing Arrangements apply.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14847

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 8 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13915J NP	2	5	..	*598.79	31.60	Fycompa [EI]

perampanel 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13971H NP	2	5	..	*598.79	31.60	Fycompa [EI]

perampanel 12 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14012L NP	2	5	..	*598.79	31.60	Fycompa [EI]

▪ STIRIPENTOL

Authority required (STREAMLINED)

11642

Severe myoclonic epilepsy in infancy (Dravet syndrome)

Clinical criteria:

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

stiripentol 250 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12103B	2	3	..	*670.03	31.60	Diacomit [EU]

stiripentol 250 mg powder for oral liquid, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12106E	2	3	..	*670.03	31.60	Diacomit [EU]

stiripentol 500 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12107F	2	3	..	*1295.91	31.60	Diacomit [EU]

stiripentol 500 mg powder for oral liquid, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12088F	2	3	..	*1295.91	31.60	Diacomit [EU]

▪ SULTHIAME

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

sulthiame 200 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2100M NP	1	2	..	163.32	31.60	Ospolot [FF]

sulthiame 50 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2099L NP	1	2	..	69.62	31.60	Ospolot [FF]

▪ SULTHIAME

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

sulthiame 200 mg tablet, 200

14016Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*318.19	31.60	Ospolot [FF]

sulthiame 50 mg tablet, 200

13916K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*126.39	31.60	Ospolot [FF]

▪ TOPIRAMATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5516

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

topiramate 200 mg tablet, 60

8166T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	31.03	31.60	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 200 [RW] [a] Tamate [AF]

▪ TOPIRAMATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5173

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

topiramate 15 mg capsule, 60

8371N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	24.77	26.22	Topamax Sprinkle [JC]

topiramate 25 mg capsule, 60

8372P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	22.77	24.22	Topamax Sprinkle [JC]

topiramate 50 mg capsule, 60

8520K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	28.99	30.44	Topamax Sprinkle [JC]

▪ TOPIRAMATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14931

Seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR

- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

topiramate 15 mg capsule, 60

14063E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*36.09	31.60	Topamax Sprinkle [JC]

NP

topiramate 25 mg capsule, 60

13905W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*32.09	31.60	Topamax Sprinkle [JC]

NP

topiramate 50 mg capsule, 60

13878K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*44.53	31.60	Topamax Sprinkle [JC]

NP

▪ TOPIRAMATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14973

Seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

topiramate 200 mg tablet, 60

14009H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*48.61	31.60	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 200 [RW] [a] Tamate [AF]

NP

▪ TOPIRAMATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5516

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

Authority required (STREAMLINED)

5325

Migraine

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 100 mg tablet, 60

8165R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.91	25.36	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 100 [RW] [a] Tamate [AF]

topiramate 25 mg tablet, 60

8163P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.76	19.21	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 25 [RW] [a] Tamate [AF]

topiramate 50 mg tablet, 60

8164Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.10	21.55	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 50 [RW] [a] Tamate [AF]

▪ TOPIRAMATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14973

Seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

Authority required (STREAMLINED)

14901

Migraine

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 100 mg tablet, 60

14008G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*34.37	31.60	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 100 [RW] [a] Tamate [AF]

topiramate 25 mg tablet, 60

13969F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 25 [RW] [a] Tamate [AF]

topiramate 50 mg tablet, 60

13913G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*26.75	28.20	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topiramate Sandoz [SZ]	[a] Epiramax 50 [RW] [a] Tamate [AF]

▪ ZONISAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4928

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

zonisamide 100 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9390F NP	2	5	..	*75.69	31.60	Zonegran [GH]

zonisamide 25 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9388D NP	1	5	..	24.65	26.10	Zonegran [GH]

zonisamide 50 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9389E NP	1	5	..	32.13	31.60	Zonegran [GH]

▪ ZONISAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14883

Partial epileptic seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

zonisamide 100 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13854E NP	4	5	..	*139.11	31.60	Zonegran [GH]

zonisamide 25 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13853D NP	2	5	..	*35.85	31.60	Zonegran [GH]

zonisamide 50 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13988F NP	2	5	..	*50.81	31.60	Zonegran [GH]

▪ ANTI-PARKINSON DRUGS

ANTICHOLINERGIC AGENTS

Tertiary amines

▪ TRIHEXYPHENIDYL (BENZHEXOL)

trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1109J NP	1	2	..	18.67	20.12	Artane [RW]

trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1110K NP	1	1	..	22.37	23.82	Artane [RW]

Ethers of tropine or tropine derivatives

▪ BENZATROPINE

benzatropine mesilate 2 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2362H NP	1	2	..	18.32	19.77	Benztrop [FF]

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11249C DP	1	..	..	118.61	31.60	Benzatropine Injection [FF]

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11255J NP	1	..	..	118.61	31.60	Benzatropine Injection [FF]

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

▪ LEVODOPA + BENSERAZIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

levodopa 100 mg + benserazide 25 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2225D NP	1	5	..	29.53	30.98	Madopar 125 [RO]

levodopa 100 mg + benserazide 25 mg modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2231K NP	1	5	..	33.09	31.60	Madopar HBS [RO]

levodopa 200 mg + benserazide 50 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2226E NP	1	5	..	39.49	31.60	Madopar [RO]

levodopa 50 mg + benserazide 12.5 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2227F NP	1	5	..	25.17	26.62	Madopar 62.5 [RO]

levodopa 100 mg + benserazide 25 mg dispersible tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8219N NP	1	5	..	35.27	31.60	Madopar Rapid 125 [RO]

levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8218M NP	1	5	..	25.17	26.62	Madopar Rapid 62.5 [RO]

levodopa 100 mg + benserazide 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2229H NP	1	5	..	29.53	30.98	Madopar 125 [RO]

levodopa 200 mg + benserazide 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2228G NP	1	5	..	39.49	31.60	Madopar [RO]

▪ LEVODOPA + CARBIDOPA

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

levodopa 100 mg + carbidopa 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1242J NP	1	5	..	32.44	31.60	[a] APO-Levodopa/Carbidopa [TX] [a] SINADOPA 100/25 [RW]	[a] Kinson [AF] [a] Sinemet 100/25 [AL]

levodopa 250 mg + carbidopa 25 mg tablet, 100

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	36.87	31.60	[a] APO-Levodopa/Carbidopa [TX]	[a] SINADOPA 250/25 [RW]

1245M [a] Sinemet [AL]

NP

▪ LEVODOPA + CARBIDOPA

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

levodopa 200 mg + carbidopa 50 mg modified release tablet, 100

1255C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	69.32	31.60	Sinemet CR [AL]

▪ LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

10197

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

11919H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*5903.55	31.60	Duodopa [VE]

▪ LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

10386

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

8970D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*11698.59	31.60	Duodopa [VE]

▪ LEVODOPA + CARBIDOPA + ENTACAPONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**

- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

Restricted benefit

Parkinson disease

Clinical criteria:

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100

8798C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*160.73	31.60	[a] Carlevent [TX] [a] Lecteva [TB]	[a] L.C.E. Sandoz [HX] [a] Stalevo 100/25/200mg [SZ]

NP

levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100

9345W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*166.51	31.60	[a] Carlevent [TX] [a] Lecteva [TB]	[a] L.C.E. Sandoz [HX] [a] Stalevo 125/31.25/200mg [SZ]

NP

levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100

8799D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*175.13	31.60	[a] Carlevent [TX] [a] Lecteva [TB]	[a] L.C.E. Sandoz [HX] [a] Stalevo 150/37.5/200mg [SZ]

NP

levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100

9292C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*188.39	31.60	[a] Carlevent [TX] [a] Lecteva [TB]	[a] L.C.E. Sandoz [HX] [a] Stalevo 200/50/200mg [SZ]

NP

levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100

8797B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*146.33	31.60	[a] Carlevent [TX] [a] Lecteva [TB]	[a] L.C.E. Sandoz [HX] [a] Stalevo 50/12.5/200mg [SZ]

NP

levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100

9344T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	4	..	*152.65	31.60	[a] Carlevent [TX] [a] Lecteva [TB]	[a] L.C.E. Sandoz [HX] [a] Stalevo 75/18.75/200mg [SZ]

NP

Adamantane derivatives

▪ AMANTADINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must not be drug induced.

amantadine hydrochloride 100 mg capsule, 100

3016R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	34.56	31.60	[a] AMANTAMED [DZ]	[a] Symmetrel 100 [NV]

NP

Dopamine agonists

▪ APOMORPHINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

10844

Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

12306Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
36	5	..	*6192.03	31.60	Movapo [TD]

NP

apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12142C NP	18	5	..	*7589.91	31.60	Apomine Solution for Infusion [IT]

apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12319J NP	36	5	..	*8179.59	31.60	Movapo PFS [TD]

▪ APOMORPHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

10844

Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12137T NP	20	5	..	*2750.67	31.60	[a] Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12133N NP	20	5	..	*2750.67	31.60	[a] Apomine Intermittent [IT]

▪ BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Restricted benefit

Parkinson disease

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1443Y	2	5	..	*32.73	31.60	Parlodel [SZ]

▪ BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

13979R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*51.99	31.60	Parlodel [SZ]

▪ CABERGOLINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

cabergoline 1 mg tablet, 30

8393R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	49.93	31.60	Cabaser [PF]

cabergoline 2 mg tablet, 30

8394T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	62.34	31.60	Cabaser [PF]

▪ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

pramipexole dihydrochloride monohydrate 1 mg tablet, 100

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	77.97	31.60	[a] APO-Pramipexole [TX]	[a] Sifrol [BY]

9153R						[a] Simipex 1 [RW]	[a] Simpral [AF]
NP							

pramipexole dihydrochloride monohydrate 125 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9151P	1	..	..	16.91	18.36	[a] APO-Pramipexole [TX] [a] Simipex 0.125 [RW]	[a] Sifrol [BY] [a] Simpral [AF]
NP							

pramipexole dihydrochloride monohydrate 250 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9152Q	1	5	..	28.24	29.69	[a] APO-Pramipexole [TX] [a] Simipex 0.25 [RW]	[a] Sifrol [BY] [a] Simpral [AF]
NP							

▪ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Parkinson disease

pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5145T	1	5	..	95.35	31.60	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3422D	1	5	..	113.40	31.60	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3418X	1	5	..	21.22	22.67	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3419Y	1	5	..	28.73	30.18	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3420B	1	5	..	44.00	31.60	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5143Q	1	5	..	59.26	31.60	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3421C	1	5	..	80.09	31.60	[a] APO-Pramipexole ER [TX] [a] SIMIPEX XR [RW]	[a] Sifrol ER [BY]
NP							

▪ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Primary severe restless legs syndrome

Clinical criteria:

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**

- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

pramipexole dihydrochloride monohydrate 125 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9393J NP	1	2	..	16.91	18.36	[a] APO-Pramipexole [TX]	[a] Sifrol [BY]
						[a] Simipex 0.125 [RW]	[a] Simpral [AF]

pramipexole dihydrochloride monohydrate 250 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9394K NP	1	2	..	28.24	29.69	[a] APO-Pramipexole [TX]	[a] Sifrol [BY]
						[a] Simipex 0.25 [RW]	[a] Simpral [AF]

▪ ROTIGOTINE

Restricted benefit

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 8 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11140H	1	5	..	111.23	31.60	Neupro [UC]

rotigotine 4 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2384L	1	5	..	90.95	31.60	Neupro [UC]

rotigotine 6 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2410W	1	5	..	101.39	31.60	Neupro [UC]

▪ ROTIGOTINE

Restricted benefit

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 2 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2385M	1	5	..	71.59	31.60	Neupro [UC]

Monoamine oxidase B inhibitors

▪ RASAGILINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Parkinson disease

rasagiline 1 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1952R NP	1	5	..	41.73	31.60	[a] Alziras [RW]	[a] Pharmacor Rasagiline [CR]
						[a] Rasagiline Lupin [HQ]	[a] Rasagiline Sandoz [SZ]
						[a] Rasagiline-Teva [EV]	
			[B]3.60	45.33	31.60	[a] Azilect [TB]	

▪ SAFINAMIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

safinamide 50 mg tablet, 30

11656L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	63.20	31.60	Xadago [CS]

NP

safinamide 100 mg tablet, 30

11666B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	112.93	31.60	Xadago [CS]

NP

▪ SELEGILINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Late stage Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

selegiline hydrochloride 5 mg tablet, 100

1973W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	53.77	31.60	Eldepryl [OX]

NP

Other dopaminergic agents

▪ ENTACAPONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

entacapone 200 mg tablet, 100

8367J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	4	..	*179.23	31.60	Comtan [SZ]

NP

▪ OPICAPONE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

opicapone 50 mg capsule, 30

13206C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	151.69	31.60	Ongentys [XY]

NP

▪ PSYCHOLEPTICS

ANTIPSYCHOTICS

Phenothiazines with aliphatic side-chain

▪ CHLORPROMAZINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1195X NP	1	..	..	34.45	31.60	Largactil [IX]

chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1201F NP	‡1	5	..	24.91	26.36	Largactil [IX]

chlorpromazine hydrochloride 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1199D NP	1	5	..	28.55	30.00	Largactil [IX]

chlorpromazine hydrochloride 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1197B NP	1	5	..	18.45	19.90	Largactil [IX]

Phenothiazines with piperidine structure

▪ PERICIAZINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

periciazine 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3053Q NP	1	5	..	22.41	23.86	Neulactil [IX]

periciazine 2.5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3052P NP	1	5	..	18.43	19.88	Neulactil [IX]

Butyrophenone derivatives

▪ HALOPERIDOL

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2768Q NP	1	..	..	24.66	26.11	Serenace [AS]

haloperidol 2 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2763K NP	‡1	5	..	23.98	25.43	Serenace [AS]

haloperidol 1.5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2767P NP	1	5	..	17.28	18.73	Serenace [AS]

haloperidol 5 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2770T NP	1	5	..	17.14	18.59	Serenace [AS]

haloperidol 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2761H NP	1	5	..	16.93	18.38	Serenace [AS]

▪ HALOPERIDOL DECANOATE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2766N NP	1	..	..	46.45	31.60	Haldol decanoate [JC]

haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules

2765M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	29.91	31.36	Haldol decanoate [JC]

Indole derivatives

▪ LURASIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

lurasidone hydrochloride 40 mg tablet, 30

10526B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.88	31.60	[a] APO-Lurasidone [TX] [a] Lavione [AF] [a] Lurasidone Sandoz [SZ] [a] Pharmacor Lurasidone [CR]	[a] Latuda [SE] [a] Lurasidone Lupin [GQ] [a] LURASIDONE SUN [RA]

lurasidone hydrochloride 80 mg tablet, 30

10529E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	54.29	31.60	[a] APO-Lurasidone [TX] [a] Lavione [AF] [a] Lurasidone Sandoz [SZ] [a] Pharmacor Lurasidone [CR]	[a] Latuda [SE] [a] Lurasidone Lupin [GQ] [a] LURASIDONE SUN [RA]

▪ ZIPRASIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5742

Acute mania or mixed episodes

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

ziprasidone 20 mg capsule, 60

9070J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	48.53	31.60	[a] Zeldox [UJ] [a] ZIPROX [RW]	[a] Ziprasidone GH [GQ]

ziprasidone 40 mg capsule, 60

9071K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	83.74	31.60	[a] Zeldox [UJ] [a] ZIPROX [RW]	[a] Ziprasidone GH [GQ]

ziprasidone 60 mg capsule, 60

9072L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	118.74	31.60	[a] Zeldox [UJ] [a] ZIPROX [RW]	[a] Ziprasidone GH [GQ]

ziprasidone 80 mg capsule, 60

9073M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	155.70	31.60	[a] Zeldox [UJ] [a] ZIPROX [RW]	[a] Ziprasidone GH [GQ]

Thioxanthene derivatives

▪ FLUPENTIXOL DECANOATE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

flupentixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules

2257T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	50.81	31.60	Fluanxol Concentrated Depot [LU]

NP

flupentixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules

2255Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	25.71	27.16	Fluanxol Depot [LU]

NP

▪ ZUCLOPENTHIXOL DECANOATE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules

8097E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	31.56	31.60	Clopixol Depot [LU]

NP

Diazepines, oxazepines, thiazepines and oxepines

▪ ASENAPINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5773

Acute mania or mixed episodes

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)

5719

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

asenapine 10 mg sublingual wafer, 60

5141N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	224.79	31.60	Saphris [OQ]

NP

asenapine 5 mg sublingual wafer, 60

5140M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	138.23	31.60	Saphris [OQ]

NP

▪ OLANZAPINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 2.5 mg tablet, 28

8170B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.95	18.40	[a] APO-OLANZAPINE [TX] [a] Olanzapine APOTEX [GX] [a] Olanzapine Sandoz [SZ]	[a] NOUMED OLANZAPINE [VO] [a] Olanzapine RBX [RA] [a] Ozin 2.5 [ZS]

NP

						[a] PRYZEX [RW]	[a] Zypine [AF]
			[B]7.83	24.78	18.40	[a] Zyprexa [PB]	

olanzapine 5 mg tablet, 28

8185T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	[a] NOUMED OLANZAPINE [VO]	[a] Olanzapine APOTEX [GX]
						[a] Olanzapine RBX [RA]	[a] Olanzapine Sandoz [SZ]
						[a] Ozin 5 [ZS]	[a] PRYZEX [RW]
						[a] Zypine [AF]	
			[B]10.17	28.04	19.32	[a] Zyprexa [PB]	

olanzapine 7.5 mg tablet, 28

8186W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.56	21.01	[a] APO-OLANZAPINE [TX]	[a] NOUMED OLANZAPINE [VO]
						[a] Olanzapine APOTEX [GX]	[a] Olanzapine RBX [RA]
						[a] Olanzapine Sandoz [SZ]	[a] Ozin 7.5 [ZS]
						[a] PRYZEX [RW]	[a] Zypine [AF]
			[B]5.87	25.43	21.01	[a] Zyprexa [PB]	

olanzapine 10 mg tablet, 28

8187X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.58	23.03	[a] APO-OLANZAPINE [TX]	[a] NOUMED OLANZAPINE [VO]
						[a] Olanzapine APOTEX [GX]	[a] Olanzapine RBX [RA]
						[a] Olanzapine Sandoz [SZ]	[a] Ozin 10 [ZS]
						[a] PRYZEX [RW]	[a] Zypine [AF]
			[B]5.86	27.44	23.03	[a] Zyprexa [PB]	

▪ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 5 mg orally disintegrating tablet, 28

3381Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	[a] APO-Olanzapine ODT [TX]	[a] Olanzapine Sandoz ODT 5 [SZ]
						[a] PRYZEX ODT [RW]	[a] Zypine ODT [AF]

olanzapine 5 mg wafer, 28

8433W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	[B]10.17	28.04	19.32	[a] Zyprexa Zydis [PB]

▪ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 10 mg orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3382B NP	1	5	..	21.58	23.03	[a] APO-Olanzapine ODT [TX]	[a] Olanzapine ODT generichealth 10 [GQ]
						[a] Olanzapine Sandoz ODT 10 [SZ]	[a] PRYZEX ODT [RW]
						[a] Zypine ODT [AF]	

olanzapine 10 mg wafer, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8434X NP	1	5	[B]11.86	33.44	23.03	[a] Zyprexa Zydis [PB]

▪ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 15 mg orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3384D NP	1	5	..	25.64	27.09	[a] APO-Olanzapine ODT [TX]	[a] Olanzapine Sandoz ODT 15 [SZ]
						[a] PRYZEX ODT [RW]	[a] Zypine ODT [AF]

olanzapine 15 mg wafer, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8952E NP	1	5	[B]13.87	39.51	27.09	[a] Zyprexa Zydis [PB]

▪ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 20 mg orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3385E NP	1	5	..	29.71	31.16	[a] APO-Olanzapine ODT [TX]	[a] Olanzapine Sandoz ODT 20 [SZ]
						[a] PRYZEX ODT [RW]	[a] Zypine ODT [AF]

olanzapine 20 mg wafer, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8953F NP	1	5	[B]13.87	43.58	31.16	[a] Zyprexa Zydis [PB]

▪ OLANZAPINE

Caution Monitor for post-injection syndrome for at least two hours after each injection.

Note Special Pricing Arrangements apply.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4304

Schizophrenia

olanzapine 210 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9294E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*323.17	31.60	Zyprexa Relprevv [PB]

olanzapine 300 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9295F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*520.57	31.60	Zyprexa Relprevv [PB]

olanzapine 405 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9303P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	346.82	31.60	Zyprexa Relprevv [PB]

▪ QUETIAPINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5611

Acute mania

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)

5639

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

quetiapine 50 mg modified release tablet, 60

9202H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	21.91	23.36	[a] APX-Quetiapine XR [TY] [a] Quetiapine Sandoz XR [SZ] [a] Tevatiapine XR [TB]	[a] QUETIAPINE-AS XR [RW] [a] Quetia XR [OW]
		[B]11.00	32.91	23.36	[a] Seroquel XR [AL]	

quetiapine 100 mg tablet, 90

8457D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	25.41	26.86	[a] APX-QUETIAPINE [TX] [a] Kaptan [ZS] [a] Quetia 100 [RW] [a] Quetiapine RBX [RA] [a] Syquet [AF]	[a] Blooms The Chemist Quetiapine [BG] [a] Pharmacor Quetiapine 100 [CR] [a] Quetiapine APOTEX [GX] [a] Quetiapine Sandoz Pharma [HX]
		[B]10.99	36.40	26.86	[a] Seroquel [AL]	

quetiapine 200 mg tablet, 60

8458E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	29.74	31.19	[a] APX-QUETIAPINE [TX] [a] Kaptan [ZS] [a] Quetia 200 [RW] [a] Quetiapine RBX [RA] [a] Syquet [AF]	[a] Blooms The Chemist Quetiapine [BG] [a] Pharmacor Quetiapine 200 [CR] [a] Quetiapine APOTEX [GX] [a] Quetiapine Sandoz Pharma [HX]
		[B]11.00	40.74	31.19	[a] Seroquel [AL]	

quetiapine 300 mg tablet, 60

8580N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.36	31.60	[a] APX-QUETIAPINE [TX]	[a] Blooms The Chemist Quetiapine [BG]
						[a] Kaptan [ZS]	[a] Pharmacor Quetiapine 300 [CR]
						[a] Quetia 300 [RW]	[a] Quetiapine APOTEX [GX]
						[a] Quetiapine RBX [RA]	[a] Quetiapine Sandoz Pharma [HX]
						[a] Syquet [AF]	
			[B]11.00	48.36	31.60	[a] Seroquel [AL]	

quetiapine 150 mg modified release tablet, 60

5458G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.41	26.86	[a] APX-Quetiapine XR [TY]	[a] Quetiapine Sandoz XR [SZ]
						[a] Quetia XR [OW]	[a] Tevatiapine XR [TB]
			[B]18.01	43.42	26.86	[a] Seroquel XR [AL]	

quetiapine 200 mg modified release tablet, 60

9203J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.05	31.60	[a] APX-Quetiapine XR [TY]	[a] QUETIAPINE-AS XR [RW]
						[a] Quetiapine Sandoz XR [SZ]	[a] Quetia XR [OW]
						[a] Tevatiapine XR [TB]	
			[B]11.00	49.05	31.60	[a] Seroquel XR [AL]	

quetiapine 300 mg modified release tablet, 60

9204K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.04	31.60	[a] APX-Quetiapine XR [TY]	[a] QUETIAPINE-AS XR [RW]
						[a] Quetiapine Sandoz XR [SZ]	[a] Quetia XR [OW]
						[a] Tevatiapine XR [TB]	
			[B]11.00	56.04	31.60	[a] Seroquel XR [AL]	

quetiapine 400 mg modified release tablet, 60

9205L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	56.51	31.60	[a] APX-Quetiapine XR [TY]	[a] QUETIAPINE-AS XR [RW]
						[a] Quetiapine Sandoz XR [SZ]	[a] Quetia XR [OW]
						[a] Tevatiapine XR [TB]	
			[B]11.00	67.51	31.60	[a] Seroquel XR [AL]	

▪ QUETIAPINE

Note No increase in the maximum quantity or number of units may be authorised.

Note Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7916

Schizophrenia

Authority required (STREAMLINED)

7927

Acute mania

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy.

Authority required (STREAMLINED)

7893

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

quetiapine 25 mg tablet, 60

8456C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.87	19.32	[a] APX-QUETIAPINE [TX]	[a] Blooms The Chemist Quetiapine [BG]
						[a] Kaptan [ZS]	[a] Pharmacor Quetiapine 25 [CR]
						[a] Quetia 25 [RW]	[a] Quetiapine APOTEX [GX]
						[a] Quetiapine RBX [RA]	[a] Quetiapine Sandoz Pharma [HX]
						[a] Syquet [AF]	

[B]11.00	28.87	19.32	[a] Seroquel [AL]	

Benzamides

▪ AMISULPRIDE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

amisulpride 100 mg/mL oral liquid, 60 mL

8736T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*144.31	31.60	Solian Solution [SW]

amisulpride 100 mg tablet, 30

8594H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.37	20.82	[a] Amisulpride Sandoz Pharma [HX]	[a] APO-Amisulpride [TX]
					[a] Solian 100 [SW]	[a] Sulprix [AF]

amisulpride 200 mg tablet, 60

8595J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	38.96	31.60	[a] Amisulpride Sandoz Pharma [HX]	[a] APO-Amisulpride [TX]
					[a] Solian 200 [SW]	[a] Sulprix [AF]

amisulpride 400 mg tablet, 60

8596K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	59.70	31.60	[a] Amipride 400 [RW]	[a] Amisulpride Sandoz Pharma [HX]
					[a] APO-Amisulpride [TX]	[a] Solian 400 [SW]
					[a] Sulprix [AF]	

Other antipsychotics

▪ ARIPIPRAZOLE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

aripiprazole 20 mg tablet, 30

8719X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	66.34	31.60	[a] Abilify [OS]	[a] Abyraz [AF]
					[a] APO-Aripiprazole [TX]	[a] Aripic Aripiprazole [LR]
					[a] Aripiprazole GH [GQ]	[a] Aripiprazole Sandoz [SZ]
					[a] ARIZOLE [RW]	[a] Tevaripiprazole [TB]

aripiprazole 30 mg tablet, 30

8720Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	77.90	31.60	[a] Abilify [OS]	[a] Abyraz [AF]
					[a] APO-Aripiprazole [TX]	[a] Aripic Aripiprazole [LR]
					[a] Aripiprazole GH [GQ]	[a] Aripiprazole Sandoz [SZ]
					[a] ARIZOLE [RW]	[a] Tevaripiprazole [TB]

aripiprazole 10 mg tablet, 30

8717T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	44.07	31.60	[a] Abilify [OS]	[a] Abyraz [AF]
					[a] APO-Aripiprazole [TX]	[a] Aripiprazole GH [GQ]
					[a] Aripiprazole Sandoz [SZ]	[a] ARIZOLE [RW]
					[a] Tevaripiprazole [TB]	

aripiprazole 15 mg tablet, 30

8718W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	56.90	31.60	[a] Abilify [OS]	[a] Abyraz [AF]
					[a] APO-Aripiprazole [TX]	[a] Aripic Aripiprazole [LR]
					[a] Aripiprazole GH [GQ]	[a] Aripiprazole Sandoz [SZ]
					[a] ARIZOLE [RW]	[a] Tevaripiprazole [TB]

aripiprazole 300 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10224D NP	1	5	..	293.37	31.60	Abilify Maintena [LU]

aripiprazole 400 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10219W NP	1	5	..	364.60	31.60	Abilify Maintena [LU]

▪ BREXPIPRAZOLE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

brexpiprazole 1 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11189X NP	1	..	..	139.42	31.60	Rexulti [LU]

brexpiprazole 2 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11188W NP	1	5	..	139.42	31.60	Rexulti [LU]

brexpiprazole 3 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11190Y NP	1	5	..	139.42	31.60	Rexulti [LU]

brexpiprazole 4 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11184P NP	1	5	..	139.42	31.60	Rexulti [LU]

▪ CARIPRAZINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

cariprazine 1.5 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12652X NP	1	5	..	102.44	31.60	Reagila [CS]

cariprazine 3 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12619E NP	1	5	..	102.44	31.60	Reagila [CS]

cariprazine 4.5 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12653Y NP	1	5	..	102.44	31.60	Reagila [CS]

cariprazine 6 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12622H NP	1	5	..	102.44	31.60	Reagila [CS]

▪ PALIPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

paliperidone 100 mg modified release injection, 1 syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5107T NP	1	5	..	284.63	31.60	Invega Sustenna [JC]

paliperidone 150 mg modified release injection, 1 syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5109X NP	1	5	..	284.63	31.60	Invega Sustenna [JC]

paliperidone 25 mg modified release injection, 1 syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5100K NP	1	5	..	95.72	31.60	Invega Sustenna [JC]

paliperidone 50 mg modified release injection, 1 syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5102M NP	1	5	..	181.21	31.60	Invega Sustenna [JC]

paliperidone 75 mg modified release injection, 1 syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5103N NP	1	5	..	233.18	31.60	Invega Sustenna [JC]

paliperidone 3 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9140C NP	1	5	..	55.49	31.60	Invega [JC]

paliperidone 6 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9141D NP	1	5	..	98.38	31.60	Invega [JC]

paliperidone 9 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9142E NP	1	5	..	142.21	31.60	Invega [JC]

▪ PALIPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

13049

Schizophrenia

Clinical criteria:

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months; OR
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle.

paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11085K NP	1	1	..	526.70	31.60	Invega Trinza [JC]

paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11072R NP	1	1	..	682.63	31.60	Invega Trinza [JC]

paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11094X NP	1	1	..	835.87	31.60	Invega Trinza [JC]

paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11066K NP	1	1	..	835.87	31.60	Invega Trinza [JC]

▪ PALIPERIDONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

13082

Schizophrenia

Clinical criteria:

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle; OR
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

paliperidone 700 mg/3.5 mL modified release injection, 3.5 mL syringe

13053B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1606.43	31.60	Invega Hafyera [JC]

paliperidone 1 g/5 mL modified release injection, 5 mL syringe

13046P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1606.43	31.60	Invega Hafyera [JC]

▪ RISPERIDONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5907

Acute mania

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

risperidone 1 mg/mL oral liquid, 100 mL

8100H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	114.99	31.60	[a] Risperdal [JC]	[a] Rixadone [AF]

risperidone 1 mg tablet, 60

3169T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.87	19.32	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
					[a] Rispernia [ZS]	[a] Rixadone [AF]

risperidone 2 mg tablet, 60

3170W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.03	24.48	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
					[a] Rispernia [ZS]	[a] Rixadone [AF]

risperidone 3 mg tablet, 60

3171X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	28.22	29.67	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
					[a] Rispernia [ZS]	[a] Rixadone [AF]

risperidone 4 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3172Y NP	1	5	..	33.37	31.60	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
						[a] Rispa [RW]	[a] Risperdal [JC]
						[a] Risperidone Sandoz [SZ]	[a] Rispernia [ZS]
						[a] Rixadone [AF]	

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6898

Severe behavioural disturbances

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

6899

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

risperidone 1 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9293D NP	‡1	2	..	114.99	31.60	[a] Risperdal [JC]	[a] Rixadone [AF]

risperidone 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8789N NP	1	2	..	17.87	19.32	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
						[a] Ozidal [RA]	[a] Rispa [RW]
						[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
						[a] Rispernia [ZS]	[a] Rixadone [AF]

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

6897

Severe behavioural disturbances

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

6938

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

risperidone 2 mg tablet, 60

9079W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	23.03	24.48	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
					[a] Rispernia [ZS]	[a] Rixadone [AF]

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5912

Bipolar I disorder

Clinical criteria:

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8780D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*186.57	31.60	Risperdal Consta [JC]

risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8781E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*240.37	31.60	Risperdal Consta [JC]

risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8782F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*293.61	31.60	Risperdal Consta [JC]

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5903

Schizophrenia

risperidone 500 microgram tablet, 20

1846E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*22.20	23.65	[a] Risperdal [JC]

risperidone 500 microgram tablet, 60

8869T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	22.20	23.65	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperidone Sandoz [SZ]	[a] Rispernia [ZS]
					[a] Rixadone [AF]	

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6898

Severe behavioural disturbances

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

6899

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

risperidone 500 microgram tablet, 20

1842Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	2	..	*22.20	23.65	[a] Risperdal [JC]

risperidone 500 microgram tablet, 60

8787L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	22.20	23.65	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperidone Sandoz [SZ]	[a] Rispernia [ZS]
					[a] Rixadone [AF]	

▪ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10020

Behavioural disturbances

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

risperidone 1 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11874Y NP	‡1	2	..	114.99	31.60	[a] Risperdal [JC]	[a] Rixadone [AF]

risperidone 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11877D NP	1	2	..	17.87	19.32	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
						[a] Ozidal [RA]	[a] Rispa [RW]
						[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
						[a] Rispernia [ZS]	[a] Rixadone [AF]

▪ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

Clinical criteria:

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

risperidone 1 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11882J NP	‡1	2	..	114.99	31.60	[a] Risperdal [JC]	[a] Rixadone [AF]

risperidone 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11879F NP	1	2	..	17.87	19.32	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]

[a] Ozidal [RA]	[a] Rispa [RW]
[a] Risperdal [JC]	[a] Risperidone Sandoz [SZ]
[a] Rispernia [ZS]	[a] Rixadone [AF]

▪ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10020

Behavioural disturbances

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

risperidone 500 microgram tablet, 20

11872W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	2	..	*22.20	23.65	[a] Risperdal [JC]

risperidone 500 microgram tablet, 60

11869Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	22.20	23.65	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
					[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Risperidone Sandoz [SZ]	[a] Rispernia [ZS]
					[a] Rixadone [AF]	

▪ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

Clinical criteria:

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

risperidone 500 microgram tablet, 20

11873X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	2	..	*22.20	23.65	[a] Risperdal [JC]

risperidone 500 microgram tablet, 60

11881H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	22.20	23.65	[a] APO-Risperidone [TX]	[a] NOUMED RISPERIDONE [VO]
						[a] Ozidal [RA]	[a] Rispa [RW]
						[a] Risperidone Sandoz [SZ]	[a] Rispernia [ZS]
						[a] Rixadone [AF]	

ANXIOLYTICS

Benzodiazepine derivatives

▪ ALPRAZOLAM

Note The panic disorder must not be attributable to some known organic factor.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Panic disorder

Clinical criteria:

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

alprazolam 500 microgram tablet, 10

11187T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.20	23.65	[a] Alprax 0.5 [AS]	[a] Kalma 0.5 [AF]

alprazolam 1 mg tablet, 10

11186R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.74	24.19	[a] Alprax 1 [AS]	[a] Kalma 1 [AF]

alprazolam 250 microgram tablet, 10

11205R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	21.74	23.19	Kalma 0.25 [AF]

▪ DIAZEPAM

diazepam 2 mg tablet, 50

5071X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.37	17.82	[a] APO-Diazepam [TX]	[a] APX-Diazepam [TY]
						[a] Valpam 2 [RW]	
			[B]2.78	19.15	17.82	[a] Antenex 2 [AF]	

diazepam 5 mg tablet, 50

5072Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.37	17.82	[a] Antenex 5 [AF]	[a] APO-Diazepam [TX]
						[a] APX-Diazepam [TY]	[a] NOUMED DIAZEPAM [VO]
						[a] Valpam 5 [RW]	
			[B]3.08	19.45	17.82	[a] Valium [IX]	

▪ DIAZEPAM

Authority required

Chronic spasticity

Population criteria:

- Patient must be under 18 years of age.

diazepam 10 mg/10 mL oral liquid, 100 mL

2669L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	45.32	31.60	Diazepam Elixir [ON]

▪ DIAZEPAM

Note Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.
Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

diazepam 2 mg tablet, 50

3161J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.37	17.82	[a] APO-Diazepam [TX]	[a] APX-Diazepam [TY]
						[a] Valpam 2 [RW]	
			[B]2.78	19.15	17.82	[a] Antenex 2 [AF]	

diazepam 5 mg tablet, 50

3162K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.37	17.82	[a] Antenex 5 [AF]	[a] APO-Diazepam [TX]
						[a] APX-Diazepam [TY]	[a] NOUMED DIAZEPAM [VO]
						[a] Valpam 5 [RW]	
			[B]3.08	19.45	17.82	[a] Valium [IX]	

▪ OXAZEPAM

oxazepam 30 mg tablet, 25

5193H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	[a] Alepam 30 [AF]	[a] APO-Oxazepam [TX]
			[B]0.84	17.01	17.62	[a] Murelax [RW]	
			[B]3.92	20.09	17.62	[a] Serepax [AS]	

oxazepam 15 mg tablet, 25

5192G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	[a] Alepam 15 [AF]	[a] Serepax [AS]

▪ OXAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam.

oxazepam 30 mg tablet, 25

3133X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.17	17.62	[a] Alepam 30 [AF]	[a] APO-Oxazepam [TX]
			[B]0.84	17.01	17.62	[a] Murelax [RW]	
			[B]3.92	20.09	17.62	[a] Serepax [AS]	

oxazepam 15 mg tablet, 25

3132W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.17	17.62	[a] Alepam 15 [AF]	[a] Serepax [AS]

▪ OXAZEPAM

Authority required
Malignant neoplasia (late stage)
Authority required
Anxiety
Clinical criteria:

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required
Anxiety
Clinical criteria:

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

oxazepam 30 mg tablet, 25

3135B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Alepam 30 [AF]	[a] APO-Oxazepam [TX]
			[B]1.68	*20.57	20.34	[a] Murelax [RW]	
			[B]7.84	*26.73	20.34	[a] Serepax [AS]	

oxazepam 15 mg tablet, 25

3134Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Alepam 15 [AF]	[a] Serepax [AS]

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

▪ NITRAZEPAM

nitrazepam 5 mg tablet, 25

5189D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	[a] Alodorm [AF]	[a] Mogadon [IL]

▪ NITRAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam.

nitrazepam 5 mg tablet, 25

2723H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.17	17.62	[a] Alodorm [AF]	[a] Mogadon [IL]

▪ NITRAZEPAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

2732T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	[a] Alodorm [AF]	[a] Mogadon [IL]

▪ TEMAZEPAM

temazepam 10 mg tablet, 25

5221T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	[a] APO-Temazepam [TX] [a] Temtabs [LN]	[a] Temaze [AF]
			[B]5.07	21.24	17.62	[a] Normison [AS]	

▪ TEMAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

temazepam 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2089Y NP	1	..	..	16.17	17.62	[a] APO-Temazepam [TX] [a] Temtabs [LN]	[a] Temaze [AF]
			[B]5.07	21.24	17.62	[a] Normison [AS]	

▪ TEMAZEPAM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

temazepam 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2088X NP	2	5	..	*18.89	20.34	[a] APO-Temazepam [TX] [a] Temtabs [LN]	[a] Temaze [AF]
			[B]10.14	*29.03	20.34	[a] Normison [AS]	

Melatonin receptor agonists

▪ MELATONIN

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note A developmental specialist is a medical practitioner who is a member of the Neurodevelopmental and Behavioural Paediatric Society of Australasia.

Note Increases in the maximum quantity to provide sufficient treatment duration for 30 days treatment per dispensing at the maximum recommended dose as per the approved Product Information, may be sought.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Insomnia

Treatment Phase: Initial

Clinical criteria:

- Patient must have Smith-Magenis Syndrome confirmed by genetic testing, **AND**
- The condition must be inadequately responsive to sleep hygiene measures, resulting in the patient experiencing a period of at least 12 consecutive weeks of impaired sleep (see definition of impaired sleep below).

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types.

Population criteria:

- Patient must be at least 2 years of age, but yet to turn 18 years of age, at treatment initiation with this drug.

Definition:

For the purposes of administering this restriction, Smith-Magenis Syndrome is confirmed by the deletion or variation of the retinoic acid induced 1 (RAI1) gene on chromosome 17p11.2

Definition:For the purposes of administering this restriction, impaired sleep is at least one of:(i) less than 6 hours of continuous sleep on at least 3 occasions over a given 5-day interval; (ii) taking at least half an hour to fall asleep on at least 3 occasions over a given 5-day interval.

Prior to seeking authorisation for this pharmaceutical benefit, document the amount of continuous sleep/sleep latency in the patient's medical records for a period of 2 consecutive weeks, but ensure the impairment has been observed for at least 12

consecutive weeks. The documented values (averages) will form baseline measurements upon which the extent of response to treatment is to be considered under the Continuing treatment listing.

The observations of continuous sleep/sleep latency may be based on any of the following, including a mix of: patient self-reporting, parental observation, documented medical history, sleep studies conducted by health professionals.

Authority required

Insomnia

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have experienced/maintained a clinically meaningful response (as defined below) to the preceding supply of this drug - document the response improvement in the patient's medical records, **AND**
- The treatment must have commenced between the ages of 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Treatment must cease if a patient is unable to achieve a clinically meaningful response on the maximum dose of melatonin specified in the Product Information.

Definition:

A clinically meaningful response to this drug is defined as at least one of:

(i) an increase in total sleep time of at least 45 minutes per night on average from baseline;

(ii) a decrease in the time it takes to fall asleep by at least 15 minutes per night on average from baseline.

melatonin 1 mg modified release tablet, 60

14188R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	72.60	31.60	Slenyto [AS]

melatonin 5 mg modified release tablet, 30

14211Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	155.23	31.60	Slenyto [AS]

▪ PSYCHOANALEPTICS

ANTIDEPRESSANTS

Non-selective monoamine reuptake inhibitors

▪ AMITRIPTYLINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

amitriptyline hydrochloride 50 mg tablet, 50

2429W

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	17.25	18.70	[a] Amitriptyline Lupin [GQ] [a] APO-Amitriptyline 50 [TX] [a] ENTRIP [RW]	[a] Amitriptyline Viatris 50 [AL] [a] APX-Amitriptyline [TY]
		[B]1.82	19.07	18.70	[a] Endep 50 [AF]	

amitriptyline hydrochloride 10 mg tablet, 50

2417F

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	16.70	18.15	[a] Amitriptyline Lupin [GQ] [a] APO-Amitriptyline 10 [TX] [a] ENTRIP [RW]	[a] Amitriptyline Viatris 10 [AL] [a] APX-Amitriptyline [TY]
		[B]1.82	18.52	18.15	[a] Endep 10 [AF]	

amitriptyline hydrochloride 25 mg tablet, 50

2418G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	16.88	18.33	[a] Amitriptyline Lupin [GQ] [a] APO-Amitriptyline 25 [TX] [a] ENTRIP [RW]	[a] Amitriptyline Viatris 25 [AL] [a] APX-Amitriptyline [TY]
		[B]1.82	18.70	18.33	[a] Endep 25 [AF]	

▪ CLOMIPRAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Cataplexy

Clinical criteria:

- The condition must be associated with narcolepsy.

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Phobic disorders

Population criteria:

- Patient must be an adult.

clomipramine hydrochloride 25 mg tablet, 50

1561E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	19.40	20.85	[a] APO-Clomipramine [TX]	[a] Placil [AF]
		[B]4.41	23.81	20.85	[a] Anafranil 25 [PB]	

▪ DOSULEPIN (DOTHIEPIN)

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

dosulepin (dothiepin) hydrochloride 25 mg capsule, 50

1357K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	16.76	18.21	[a] Dosulepin Viatris [MQ]
		[B]1.81	18.57	18.21	[a] Dothep 25 [AF]

dosulepin (dothiepin) hydrochloride 75 mg tablet, 30

1358L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	16.76	18.21	[a] Dosulepin Viatris 75 [AL]
		[B]1.81	18.57	18.21	[a] Dothep 75 [AF]

▪ IMIPRAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

imipramine hydrochloride 10 mg tablet, 50

2420J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17.84	19.29	Tofranil 10 [GH]

▪ IMIPRAMINE

Note Pharmaceutical benefits that have the form imipramine hydrochloride 25 mg tablet in a pack size of 50 can be substituted for a pack size of 100 in the case of a shortage.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

imipramine hydrochloride 25 mg tablet, 50

2421K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	21.10	22.55	[a] Tofranil 25 [GH]

imipramine hydrochloride 25 mg tablet, 100

12113M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.5	2	..	*27.67	29.12	[a] Imipramine (Leading) [QY]

▪ NORTRIPTYLINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depression

Clinical criteria:

- The treatment must be for use when other anti-depressant therapy has failed.

Restricted benefit

Major depression

Clinical criteria:

- The treatment must be for use when other anti-depressant therapy is contraindicated.

nortriptyline 10 mg tablet, 50

2522R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17.42	18.87	[a] NortriTABS 10 mg [GH]
		[B]0.50	17.92	18.87	[a] Allegron [RW]

nortriptyline 25 mg tablet, 50

2523T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	18.33	19.78	[a] NortriTABS 25 mg [GH]
		[B]1.00	19.33	19.78	[a] Allegron [RW]

Selective serotonin reuptake inhibitors

▪ CITALOPRAM

Restricted benefit

Major depressive disorders

citalopram 10 mg tablet, 28

8702B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] Celapram [AF]	[a] Talam [RW]

citalopram 20 mg tablet, 28

8220P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Citalopram [TX] [a] Celapram [AF] [a] NOUMED CITALOPRAM [VO]	[a] APX-Citalopram [TY] [a] Citalopram Sandoz [SZ] [a] Talam [RW]
		[B]12.95	29.32	17.82	[a] Cipramil [LU]	

citalopram 40 mg tablet, 28

8703C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.41	17.86	[a] APO-Citalopram [TX] [a] Citalopram Sandoz [SZ] [a] Talam [RW]	[a] Celapram [AF] [a] NOUMED CITALOPRAM [VO]

▪ ESCITALOPRAM

Restricted benefit

Major depressive disorders

escitalopram 10 mg tablet, 28

8700X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Escitalopram [TX] [a] Blooms Escitalopram [BG] [a] Cilopam-S [ZS] [a] Escitalopram Sandoz [HX] [a] Lexam 10 [RW] [a] NOUMED ESCITALOPRAM [VO]	[a] APX-Escitalopram [TY] [a] Blooms the Chemist Escitalopram [IB] [a] Escitalopram GH [HQ] [a] Esipram [CF] [a] LoxaLate [AF]
		[B]13.98	30.35	17.82	[a] Lexapro [LU]	

escitalopram 20 mg tablet, 28

8701Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Escitalopram [TX] [a] Blooms Escitalopram [BG] [a] Cilopam-S [ZS] [a] Escitalopram Sandoz [HX] [a] Lexam 20 [RW] [a] NOUMED ESCITALOPRAM [VO]	[a] APX-Escitalopram [TY] [a] Blooms the Chemist Escitalopram [IB] [a] Escitalopram GH [HQ] [a] Esipram [CF] [a] LoxaLate [AF]
		[B]14.33	30.70	17.82	[a] Lexapro [LU]	

▪ ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

escitalopram 10 mg tablet, 28

9432K (NP)

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	16.37	17.82	[a] APO-Escitalopram [TX] [a] Blooms Escitalopram [BG] [a] Escitalopram Sandoz [HX] [a] Lexam 10 [RW] [a] NOUMED ESCITALOPRAM [VO]	[a] APX-Escitalopram [TY] [a] Escitalopram GH [HQ] [a] Esipram [CF] [a] LoxaLate [AF]
			[B]13.98	30.35	17.82	[a] Lexapro [LU]	

escitalopram 20 mg tablet, 28

9433L (NP)

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	16.37	17.82	[a] APO-Escitalopram [TX] [a] Blooms Escitalopram [BG] [a] Escitalopram Sandoz [HX] [a] Lexam 20 [RW]	[a] APX-Escitalopram [TY] [a] Escitalopram GH [HQ] [a] Esipram [CF] [a] NOUMED ESCITALOPRAM [VO]
			[B]14.33	30.70	17.82	[a] Lexapro [LU]	

▪ ESCITALOPRAM

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

escitalopram 20 mg/mL oral liquid, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10181W NP	‡1	5	..	39.43	31.60	Lexapro [LU]

▪ FLUOXETINE

Restricted benefit

Major depressive disorders

Clinical criteria:

- Patient must be receiving this drug under this restriction at a dose of 10 mg; OR
- Patient must be receiving this drug under this restriction where a 10 mg strength is required to administer the total dose.

Restricted benefit

Obsessive-compulsive disorder

Clinical criteria:

- Patient must be receiving this drug under this restriction at a dose of 10 mg; OR
- Patient must be receiving this drug under this restriction where a 10 mg strength is required to administer the total dose.

fluoxetine 10 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13834D NP	1	5	..	59.37	31.60	Fluoxetine Capsules 10 mg (Medreich, UK) [LM]

▪ FLUOXETINE

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

fluoxetine 20 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1434L NP	1	5	..	17.37	18.82	[a] APO-Fluoxetine [TX]	[a] Blooms the Chemist Fluoxetine [BG]
						[a] BTC Fluoxetine [JB]	[a] FLUOTEX [RF]
						[a] Fluoxetine APOTEX [TY]	[a] Fluoxetine generichealth [GQ]
						[a] Fluoxetine Sandoz [SZ]	[a] NOUMED FLUOXETINE [VO]
						[a] Zactin [AF]	
			[B]1.10	18.47	18.82	[a] Prozac 20 [LY]	

fluoxetine 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8270G NP	1	5	..	17.37	18.82	Zactin Tablet [AF]

▪ FLUVOXAMINE

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

fluvoxamine maleate 100 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8174F NP	1	5	..	22.03	23.48	[a] APO-Fluvoxamine [TX]	[a] Faverin 100 [RW]
						[a] Movox 100 [AF]	
			[B]3.50	25.53	23.48	[a] Luvox [GO]	

fluvoxamine maleate 50 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8512B NP	1	5	..	19.13	20.58	[a] APO-Fluvoxamine [TX]	[a] Faverin 50 [RW]
						[a] Movox 50 [AL]	
			[B]3.49	22.62	20.58	[a] Luvox [GO]	

▪ PAROXETINE

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Panic disorder

paroxetine 20 mg tablet, 30

2242B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.37	18.82	[a] APO-Paroxetine [TX]	[a] APX-Paroxetine [TY]
					[a] Blooms The Chemist Paroxetine [BG]	[a] Extine 20 [RW]
					[a] Noumed Paroxetine [VO]	[a] Paroxetine GH [GQ]
					[a] Paroxetine Sandoz [SZ]	[a] Paxtine [AF]
		[B]2.43	19.80	18.82	[a] Aropax [AS]	

▪ SERTRALINE

Restricted benefit

Major depressive disorders

sertraline 100 mg tablet, 30

2237R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Sertraline [TX]	[a] Eleva 100 [AF]
					[a] NOUMED SERTRALINE [VO]	[a] Sertra 100 [RW]
					[a] Sertraline generichealth [GQ]	[a] Sertraline Sandoz [SZ]
					[a] Setrona [RA]	
		[B]5.58	21.95	17.82	[a] Zoloft [UJ]	

sertraline 50 mg tablet, 30

2236Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Sertraline [TX]	[a] Eleva 50 [AF]
					[a] NOUMED SERTRALINE [VO]	[a] Sertra 50 [RW]
					[a] Sertraline generichealth [GQ]	[a] Sertraline Sandoz [SZ]
					[a] Setrona [RA]	
		[B]5.58	21.95	17.82	[a] Zoloft [UJ]	

▪ SERTRALINE

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Panic disorder

Clinical criteria:

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

sertraline 100 mg tablet, 30

8837D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Sertraline [TX]	[a] Eleva 100 [AF]
					[a] NOUMED SERTRALINE [VO]	[a] Sertra 100 [RW]
					[a] Sertraline generichealth [GQ]	[a] Sertraline Sandoz [SZ]
		[B]5.58	21.95	17.82	[a] Zoloft [UJ]	

sertraline 50 mg tablet, 30

8836C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.37	17.82	[a] APO-Sertraline [TX]	[a] Eleva 50 [AF]
					[a] NOUMED SERTRALINE [VO]	[a] Sertra 50 [RW]
					[a] Sertraline generichealth [GQ]	[a] Sertraline Sandoz [SZ]
		[B]5.58	21.95	17.82	[a] Zoloft [UJ]	

Monoamine oxidase inhibitors, non-selective

▪ PHENELZINE

Caution This drug is an irreversible monoamine oxidase inhibitor.

Restricted benefit

Depression

Clinical criteria:

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

phenelzine 15 mg tablet, 100

2856H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	67.26	31.60	Nardil [LM]

phenelzine 15 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13148B	2	1	..	*174.31	31.60	Nardil (Canada) [DZ]

▪ TRANYLCYPROMINE

Caution This drug is an irreversible monoamine oxidase inhibitor.

tranylcypromine 10 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2444P	1	2	..	51.78	31.60	Parnate [GH]

Monoamine oxidase A inhibitors

▪ MOCLOBEMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

moclobemide 150 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1900B NP	1	5	..	20.06	21.51	[a] Amira 150 [AF] [a] Moclobemide Sandoz [SZ]	[a] Clobemix [XT]
			[B]2.03	22.09	21.51	[a] Aurorix [GO]	

moclobemide 300 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8003F NP	1	5	..	24.47	25.92	[a] Amira 300 [AF] [a] Moclobemide Sandoz [SZ]	[a] Clobemix [XT]
			[B]2.03	26.50	25.92	[a] Aurorix 300 mg [GO]	

Other antidepressants

▪ DESVENLAFAXINE

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

desvenlafaxine 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10231L NP	1	5	..	23.59	25.04	[a] BTC Desvenlafaxine [BG] [a] DESVEN [RW]	[a] Desfax [AF] [a] Desvenlafaxine Sandoz [SZ]

desvenlafaxine 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10245F NP	1	5	..	23.59	25.04	[a] APO-Desvenlafaxine MR [TX]	[a] Desvenlafaxine GH XR [GQ]

desvenlafaxine 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9367B NP	1	5	..	23.59	25.04	[a] Pristiq [PF]

▪ DESVENLAFAXINE

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

desvenlafaxine 50 mg modified release tablet, 28

10234P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.71	23.16	[a] APO-Desvenlafaxine MR [TX]	[a] Desvenlafaxine GH XR [GQ]

desvenlafaxine 50 mg modified release tablet, 28

10241B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.71	23.16	[a] BTC Desvenlafaxine [BG] [a] DESVEN [RW]	[a] Desfax [AF] [a] Desvenlafaxine Sandoz [SZ]

desvenlafaxine 50 mg modified release tablet, 28

9366Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	21.71	23.16	[a] Pristiq [PF]

▪ DULOXETINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

duloxetine 30 mg enteric capsule, 28

9155W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.73	19.18	[a] APO-Duloxetine [TX] [a] Duloxetine Sandoz [HX] [a] DYTREX 30 [RW]	[a] Duloxecor [CR] [a] Duloxetine Sandoz 30 [SZ] [a] Tixol [AL]
			[B]15.24	32.97	19.18	[a] Cymbalta [LY]	

duloxetine 60 mg enteric capsule, 28

9156X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	[a] APO-Duloxetine [TX] [a] Duloxetine Sandoz [HX] [a] DYTREX 60 [RW]	[a] Duloxecor [CR] [a] Duloxetine Sandoz 60 [SZ] [a] Tixol [AL]
			[B]13.89	31.76	19.32	[a] Cymbalta [LY]	

▪ LITHIUM CARBONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

lithium carbonate 250 mg tablet, 200

3059B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	49.57	31.60	Lithicarb [AS]

lithium carbonate 450 mg modified release tablet, 100

8290H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*81.13	31.60	Quilonum SR [AS]

▪ MIANSERIN

Caution Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe depression

mianserin hydrochloride 10 mg tablet, 50

1627P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	21.26	22.71	Lumin 10 [AF]

mianserin hydrochloride 20 mg tablet, 50

1628Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	29.91	31.36	Lumin 20 [AF]

▪ MIRTAZAPINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

mirtazapine 15 mg tablet, 30

9365X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.60	18.05	[a] APX-Mirtazapine [TY]	[a] Axit 15 [AF]
					[a] Blooms The Chemist Mirtazapine [BG]	[a] MIRTANZA [RF]
					[a] Mirtazapine Sandoz [SZ]	

mirtazapine 15 mg orally disintegrating tablet, 30

8855C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.72	19.17	MIRTANZA ODT [RF]

mirtazapine 30 mg tablet, 30

8513C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.37	18.82	[a] APX-Mirtazapine [TY]	[a] Axit 30 [AF]
					[a] Blooms The Chemist Mirtazapine [BG]	[a] MIRTANZA [RF]
					[a] Mirtazapine Sandoz [SZ]	[a] NOUMED MIRTAZAPINE [VO]
		[B]5.86	23.23	18.82	[a] Avanza [AL]	

mirtazapine 30 mg orally disintegrating tablet, 30

8856D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18.24	19.69	MIRTANZA ODT [RF]

mirtazapine 45 mg tablet, 30

8883M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.62	20.07	[a] APX-Mirtazapine [TY]	[a] Axit 45 [AF]
					[a] Blooms The Chemist Mirtazapine [BG]	[a] MIRTANZA [RF]
					[a] Mirtazapine Sandoz [SZ]	[a] NOUMED MIRTAZAPINE [VO]

mirtazapine 45 mg orally disintegrating tablet, 30

8857E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	20.53	21.98	MIRTANZA ODT [RF]

▪ REBOXETINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

reboxetine 4 mg tablet, 60

8583R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	40.17	31.60	Edronax [PF]

▪ VENLAFAXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

venlafaxine 150 mg modified release capsule, 28

8302Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.87	19.32	[a] APO-Venlafaxine XR [TX]	[a] Blooms the Chemist Venlafaxine XR [IB]
					[a] Elaxine SR 150 [RW]	[a] Enlafax-XR [AF]
					[a] Sandoz Venlafaxine XR [HX]	[a] Venlafaxine generichealth XR [GQ]
		[B]1.96	19.83	19.32	[a] Efexor-XR [UJ]	

venlafaxine 37.5 mg modified release capsule, 28

8868R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	16.59	18.04	[a] Efexor-XR [UJ]	[a] Elaxine SR 37.5 [RW]

venlafaxine 75 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8301X NP	1	5	..	17.37	18.82	[a] APO-Venlafaxine XR [TX]	[a] Blooms the Chemist Venlafaxine XR [IB]
						[a] Elaxine SR 75 [RW]	[a] Enlafax-XR [AF]
						[a] Sandoz Venlafaxine XR [HX]	[a] Venlafaxine generichealth XR [GQ]
			[B]2.00	19.37	18.82	[a] Efexor-XR [UJ]	

PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

Centrally acting sympathomimetics

▪ ARMODAFINIL

Note This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or modafinil.

Authority required

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamfetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**

- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Narcolepsy

Treatment Phase: Continuing or change of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with modafinil for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

armodafinil 50 mg tablet, 30

10922W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*103.57	31.60	Nuvigil [TB]

armodafinil 150 mg tablet, 30

10912H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	150.36	31.60	Nuvigil [TB]

armodafinil 250 mg tablet, 30

10919Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	244.95	31.60	Nuvigil [TB]

▪ ATOMOXETINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7876

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatrician or psychiatrist.

Clinical criteria:

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Authority required (STREAMLINED)

7890

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

atomoxetine 10 mg capsule, 28

9092M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*75.15	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

atomoxetine 100 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9290Y	1	5	..	53.55	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

atomoxetine 18 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9093N	2	5	..	*75.15	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

atomoxetine 25 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9094P	2	5	..	*75.15	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

atomoxetine 40 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9095Q	2	5	..	*75.15	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

atomoxetine 60 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9096R	2	5	..	*75.15	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

atomoxetine 80 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9289X	1	5	..	53.55	31.60	[a] APO-Atomoxetine [TX]	[a] Atomoxetine Sandoz [SZ]

▪ DEXAMFETAMINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

Authority required

Narcolepsy

dexamfetamine sulfate 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1165H (NP)	1	5	..	25.23	26.68	Aspen Pharma Pty Ltd [AS]

▪ LISDEXAMFETAMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 70 mg with this drug.

Population criteria:

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

lisdexamfetamine dimesilate 60 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11897E NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 30 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10486X NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 20 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11884L NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 70 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10492F NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10474G NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 40 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11898F NP	1	5	..	100.65	31.60	Vyvanse [TK]

▪ METHYLPHENIDATE

Note Where an increase in maximum quantity is sought, under no circumstances will a quantity beyond 2 times the listed quantity be approved.

Note No increase in the maximum number of repeats may be authorised.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

methylphenidate hydrochloride 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8839F NP	1	5	..	27.97	29.42	[a] Artige [NM]
			[B]3.76	31.73	29.42	[a] Ritalin 10 [NV]

▪ METHYLPHENIDATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

methylphenidate hydrochloride 36 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2388Q NP	1	5	..	59.59	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

methylphenidate hydrochloride 18 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2387P NP	1	5	..	52.25	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

methylphenidate hydrochloride 27 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2172H NP	1	5	..	55.91	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

methylphenidate hydrochloride 54 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2432B NP	1	5	..	67.70	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR

- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

methylphenidate hydrochloride 40 mg modified release capsule, 30

2283E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	55.13	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

methylphenidate hydrochloride 10 mg modified release capsule, 30

3440C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	38.04	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

methylphenidate hydrochloride 20 mg modified release capsule, 30

2276T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	46.27	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

methylphenidate hydrochloride 30 mg modified release capsule, 30

2280B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	52.87	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

methylphenidate hydrochloride 60 mg modified release capsule, 30

12116Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	67.46	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

▪ MODAFINIL

Note This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or armodafinil.

Authority required

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamfetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Narcolepsy

Treatment Phase: Continuing or change of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with armodafinil for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

modafinil 100 mg tablet, 60

8816B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*133.99	31.60	[a] APO-Modafinil [TX]	[a] Modafin [RW]
					[a] Modafinil GH [GQ]	[a] Modafinil Mylan [AF]
					[a] Modafinil Sandoz [SZ]	[a] Modafinil Viatris [AL]
		[B]10.80	*144.79	31.60	[a] Modavigil [TB]	

ANTI-DEMENTIA DRUGS

Anticholinesterases

▪ DONEPEZIL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

13938

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

donepezil hydrochloride 10 mg tablet, 28

2479L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.33	20.78	[a] APO-Donepezil [TX]	[a] Arazil [AF]
					[a] Aridon 10 [RW]	[a] Aridon APN 10 [RF]
					[a] Donepezil GH [HQ]	[a] Donepezil Sandoz [SZ]
					[a] NOUMED DONEPEZIL [VO]	
		[B]6.09	25.42	20.78	[a] Aricept [PF]	

donepezil hydrochloride 5 mg tablet, 28

2532G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.33	20.78	[a] APO-Donepezil [TX]	[a] Arazil [AF]
					[a] Aridon 5 [RW]	[a] Aridon APN 5 [RF]
					[a] Donepezil GH [HQ]	[a] Donepezil Sandoz [SZ]
					[a] NOUMED DONEPEZIL [VO]	
		[B]6.13	25.46	20.78	[a] Aricept [PF]	

▪ DONEPEZIL

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

donepezil hydrochloride 10 mg tablet, 28

8496E

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	19.33	20.78	[a] APO-Donepezil [TX]	[a] Arazil [AF]
						[a] Aridon 10 [RW]	[a] Aridon APN 10 [RF]
						[a] Donepezil GH [HQ]	[a] Donepezil Sandoz [SZ]
						[a] NOUMED DONEPEZIL [VO]	
			[B]6.09	25.42	20.78	[a] Aricept [PF]	

donepezil hydrochloride 5 mg tablet, 28

8495D

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1		5	..	19.33	20.78	[a] APO-Donepezil [TX]	[a] Arazil [AF]
						[a] Aridon 5 [RW]	[a] Aridon APN 5 [RF]
						[a] Donepezil GH [HQ]	[a] Donepezil Sandoz [SZ]
						[a] NOUMED DONEPEZIL [VO]	
			[B]6.13	25.46	20.78	[a] Aricept [PF]	

▪ GALANTAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

13938

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;
Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

galantamine 16 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2537M NP	1	5	..	40.22	31.60	[a] APO-Galantamine MR [TX] [a] Gamine XR [RW]	[a] Galantyl [AF] [a] Reminyl [JC]

galantamine 24 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2531F NP	1	5	..	45.35	31.60	[a] APO-Galantamine MR [TX] [a] Gamine XR [RW]	[a] Galantyl [AF] [a] Reminyl [JC]

galantamine 8 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2463P NP	1	5	..	35.34	31.60	[a] APO-Galantamine MR [TX] [a] Gamine XR [RW]	[a] Galantyl [AF] [a] Reminyl [JC]

▪ GALANTAMINE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

galantamine 16 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8771P	1	5	..	40.22	31.60	[a] APO-Galantamine MR [TX] [a] Gamine XR [RW]	[a] Galantyl [AF] [a] Reminyl [JC]

galantamine 24 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8772Q	1	5	..	45.35	31.60	[a] APO-Galantamine MR [TX] [a] Gamine XR [RW]	[a] Galantyl [AF] [a] Reminyl [JC]

galantamine 8 mg modified release capsule, 28

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	35.34	31.60	[a] APO-Galantamine MR [TX]	[a] Galantyl [AF]

8770N [a] Gamine XR [RW] [a] Reminyl [JC]

▪ RIVASTIGMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

13938

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

rivastigmine 9.5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2551G NP	1	5	..	82.96	31.60	Exelon Patch 10 [NV]

rivastigmine 4.6 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2477J NP	1	5	..	82.96	31.60	Exelon Patch 5 [NV]

rivastigmine 1.5 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2475G NP	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 3 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2493F NP	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 4.5 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2494G NP	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 6 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2526Y NP	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 13.3 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10538P NP	1	5	..	82.96	31.60	Exelon Patch 15 [NV]

▪ RIVASTIGMINE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

rivastigmine 9.5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9162F	1	5	..	82.96	31.60	Exelon Patch 10 [NV]

rivastigmine 4.6 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9161E	1	5	..	82.96	31.60	Exelon Patch 5 [NV]

rivastigmine 1.5 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8497F	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 3 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8498G	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 4.5 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8499H	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 6 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8500J	1	5	..	64.82	31.60	Exelon [NV]

rivastigmine 13.3 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10541T	1	5	..	82.96	31.60	Exelon Patch 15 [NV]

Other anti-dementia drugs

▪ MEMANTINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

13966

Moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

memantine hydrochloride 10 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2492E NP	1	5	..	43.66	31.60	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ]	[a] Ebixa [LU] [a] Memanxa [RW]

memantine hydrochloride 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2513G NP	1	5	..	43.66	31.60	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ]	[a] Ebixa [LU]

▪ MEMANTINE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

memantine hydrochloride 10 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1956Y	1	5	..	43.66	31.60	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ]	[a] Ebixa [LU] [a] Memanxa [RW]

memantine hydrochloride 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9306T	1	5	..	43.66	31.60	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ]	[a] Ebixa [LU]

OTHER NERVOUS SYSTEM DRUGS

PARASYMPATHOMIMETICS

Anticholinesterases

PYRIDOSTIGMINE

pyridostigmine bromide 10 mg tablet, 50

2724J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*26.37	27.82	Mestinon [IL]

pyridostigmine bromide 180 mg modified release tablet, 50

2608G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*95.49	31.60	Mestinon Timespan [IL]

pyridostigmine bromide 60 mg tablet, 150

1959D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	50.74	31.60	Mestinon [IL]

Choline esters

BETHANECHOL

bethanechol chloride 10 mg tablet, 100

1062X

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	31.30	31.60	Uro-Carb [YN]

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6881

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

bupropion hydrochloride 150 mg modified release tablet, 90

8710K

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	170.49	31.60	Zyban [AS]

BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6882

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**

- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

bupropion hydrochloride 150 mg modified release tablet, 30

8465M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	64.90	31.60	Zyban [AS]

▪ NICOTINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Nicotine dependence

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 14 mg/24 hours patch, 28

5572G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	51.34	31.60	Nicotinell Step 2 [ON]

nicotine 21 mg/24 hours patch, 28

3414Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	51.34	31.60	Nicotinell Step 1 [ON]

nicotine 21 mg/24 hours patch, 28

5465P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	51.34	31.60	Nicabate P [GJ]

nicotine 7 mg/24 hours patch, 28

5573H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	51.34	31.60	Nicotinell Step 3 [ON]

nicotine 25 mg/16 hours patch, 28

10076H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	51.34	31.60	nicorette 16hr Invisipatch [JT]

▪ NICOTINE

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Nicotine dependence

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition.

nicotine 21 mg/24 hours patch, 28

5571F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	51.34	31.60	Nicotinell Step 1 [ON]

▪ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6885

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

5469W

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	78.94	31.60	[a] Champix [PF]	[a] PHARMACOR VARENICLINE [CR]
					[a] VARENAPIX [TX]	[a] Varenicline Viatris [AF]

▪ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7483

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received treatment with this drug during this current course of treatment.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

9129L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*145.97	31.60	[a] Champix [PF]	[a] PHARMACOR VARENICLINE [CR]
					[a] VARENAPIX [TX]	[a] Varenicline Viatris [AF]

▪ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
Note The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.
Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6871

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9128K NP	‡1	..	..	69.00	31.60	[a] Champix [PF]	[a] PHARMACOR VARENICLINE [CR]
						[a] VARENAPIX [TX]	

Drugs used in alcohol dependence

▪ ACAMPROSATE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
5366
Alcohol dependence
Clinical criteria:

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

acamprosate calcium 333 mg enteric tablet, 180

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8357W NP	1	1	..	79.25	31.60	[a] Acamprosate Mylan [AL]	[a] ACAMPROSATE VIATRIS [MQ]
						[a] APO-Acamprosate [TX]	[a] Campral [AF]

▪ NALTREXONE

Caution Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
13967
Alcohol dependence
Clinical criteria:

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.

naltrexone hydrochloride 50 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8370M NP	1	1	..	105.43	31.60	[a] ARX-NALTREXONE [XT]	[a] Naltrexone GH [GQ]

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

▪ AMIFAMPRIDINE

Note No increase in the maximum number of repeats may be authorised.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required
Lambert-Eaton myasthenic syndrome (LEMS)
Clinical criteria:

- The condition must not be any of: (i) myasthenia gravis, (ii) Guillain-Barre syndrome.

Treatment criteria:

- Must be treated by a prescriber type identifying as at least one of the following: (i) a clinical immunologist, (ii) a neurologist, (iii) a medical practitioner working under the direct supervision of one of these mentioned specialists.

amifampridine 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13032X	2	5	..	*4461.39	31.60	Ruzurgi [OJ]

▪ RILUZOLE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Amyotrophic lateral sclerosis
Treatment Phase: Initial treatment
Clinical criteria:

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**

- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority required

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

riluzole 50 mg tablet, 56

8664B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	136.37	31.60	[a] APO-Riluzole [TX]	[a] Pharmacor Riluzole [CR]
					[a] Rilutek [SW]	[a] Riluzole Sandoz [SZ]

riluzole 50 mg/10 mL oral liquid, 300 mL

11662T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*205.55	31.60	Teglutik [CS]

▪ TAFAMIDIS

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Transthyretin amyloid cardiomyopathy

Treatment Phase: First PBS-subsidised prescription for this drug

Clinical criteria:

- The condition must have documented evidence of transthyretin precursor protein present, **AND**
- Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; OR
- Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement, **AND**
- Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; OR
- Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug, **AND**
- Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2.

Treatment criteria:

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of clinical findings to establish the diagnosis:

In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below:

Confirm the following has been completed:

(1) amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR

(2) bone scintigraphy with grade 2-3 finding AND

(3) Confirm that there are negative results for monoclonal protein on each of the following three tests:

(a) serum immunofixation (also known as protein electrophoresis)

(b) urine immunofixation

(c) serum free light chains blood test

State which of (1) to (3) above has been completed, as well as the:

(i) date of the finding,

(ii) imaging/pathology report number/code that links the finding to the patient,

(iii) name of the amyloid expert centre in this authority application (if applicable).

For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that:

(i) imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and

(ii) that the imaging report is stored in the patient's medical records.

State the date that the imaging was performed and the thickness (in mm) in this authority application.

Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following:

(i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The Australian Amyloid Network provides a list of clinic centres that manage amyloidosis. It also provides a list of Australian anatomical pathology laboratories to be contacted for tissue review and immunohistochemistry for amyloid typing. For the purposes of this restriction, these providers are considered to be amyloid expert centres.

Authority required

Transthyretin amyloid cardiomyopathy

Treatment Phase: Second and subsequent PBS-subsidised prescriptions for this drug

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2, **AND**
- The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure, **AND**
- The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device.

Treatment criteria:

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no).

If 'no', continued PBS subsidy is available.

If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent.

Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.

If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tafamidis 61 mg capsule, 30

14100D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	10022.60	31.60	Vyndamax [PF]

▪ TETRABENAZINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5340

Hyperkinetic extrapyramidal disorders

tetrabenazine 25 mg tablet, 112

1330B

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	236.48	31.60	[a] iNova Pharmaceuticals (Australia) Pty Ltd [IL]	[a] Tetrabenazine SUN [RA]

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

ANTIPROTOZOALS

AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

Other agents against amoebiasis and other protozoal diseases

ATOVAQUONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5609

Mild to moderate Pneumocystis carinii pneumonia

Population criteria:

- Patient must be an adult, **AND**
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

atovaquone 750 mg/5 mL oral liquid, 210 mL

8300W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	982.48	31.60	Wellvone [AS]

ANTIMALARIALS

Biguanides

ATOVAQUONE + PROGUANIL

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

Population criteria:

- Patient must be aged 3 years or older.

Clinical criteria:

- The treatment must be used where quinine containing regimens are inappropriate.

atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

9439T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	68.53	31.60	[a] AtovaquoPro Lupin 250/100 [GQ]	[a] Malarone [GK]

Methanolquinolines

QUININE

Caution Severe thrombocytopenia has been reported with this drug.

Authority required (STREAMLINED)

5633

Malaria

quinine sulfate dihydrate 300 mg tablet, 50

1975Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	22.28	23.73	Quinate [RW]

Artemisinin and derivatives, combinations

ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

Clinical criteria:

- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18

5296R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	101.92	31.60	Riamet 20mg/120mg Dispersible [NV]

▪ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

artemether 20 mg + lumefantrine 120 mg tablet, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9498X	1	..	..	83.79	31.60	Riamet [NV]

▪ ANTHELMINTICS

ANTITREMATODALS

Quinoline derivatives and related substances

▪ PRAZIQUANTEL

Authority required (STREAMLINED)

5659

Schistosomiasis

praziquantel 600 mg tablet, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9447F NP	1	..	..	39.06	31.60	Biltricide [BN]

ANTINEMATODAL AGENTS

Benzimidazole derivatives

▪ ALBENDAZOLE

Authority required (STREAMLINED)

5607

Hydatid disease

Clinical criteria:

- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

albendazole 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8459F	1	2	..	116.31	31.60	Eskazole [AS]

▪ ALBENDAZOLE

Authority required (STREAMLINED)

5680

Tapeworm infestation

albendazole 200 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8503M NP	1	1	..	29.19	30.64	Zentel [AS]

▪ ALBENDAZOLE

Authority required (STREAMLINED)

5817

Whipworm infestation

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)

5712

Strongyloidiasis

Authority required (STREAMLINED)

5797

Hookworm infestation

albendazole 200 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9047E NP	1	..	..	29.19	30.64	Zentel [AS]

Tetrahydropyrimidine derivatives

▪ PYRANTEL

pyrantel 125 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3047J NP	1	..	..	18.05	19.50	Anthel 125 [AF]

pyrantel 250 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3048K NP	1	..	..	22.45	23.90	Anthel 250 [AF]

Avermectines

▪ IVERMECTIN

Authority required (STREAMLINED)

4319

Onchocerciasis

ivermectin 3 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8359Y NP	1	..	..	31.04	31.60	Stromectol [MK]

▪ IVERMECTIN

Authority required (STREAMLINED)

4328

Strongyloidiasis

Authority required (STREAMLINED)

4565

Crusted (Norwegian) scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Authority required (STREAMLINED)

4566

Human sarcoptic scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Note This drug is not PBS-subsidised for first line treatment of typical scabies.

Authority required (STREAMLINED)

12604

Human sarcoptic scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander, **AND**
- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

ivermectin 3 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2868Y NP	2	2	..	*48.63	31.60	Stromectol [MK]

▪ ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

ECTOPARASITICIDES, INCL. SCABICIDES

Pyrethrines, incl. synthetic compounds

▪ PERMETHRIN

permethrin 5% cream, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3054R NP	‡1	1	..	20.78	22.23	Lyclear [ON]

▪ RESPIRATORY SYSTEM

▪ NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Other nasal preparations

▪ MUPIROCIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6647

Staphylococcus aureus infection

Clinical criteria:

- Patient must have nasal colonisation with the bacteria.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

mupirocin 2% ointment, 3 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9440W NP	‡1	..	..	26.98	28.43	Bactroban [GK]

mupirocin 2% ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11822F NP	‡1	..	..	26.98	28.43	Mupirocin Nasal (Medsurge) [DZ]

▪ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

ADRENERGICS, INHALANTS

Selective beta-2-adrenoreceptor agonists

▪ FORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8239P NP	‡1	5	..	24.43	25.88	Oxis Turbuhaler [AP]

formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8136F NP	1	5	..	30.45	31.60	Foradile [SZ]

formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8240Q NP	‡1	5	..	29.95	31.40	Oxis Turbuhaler [AP]

▪ INDACATEROL

Note This drug is not PBS-subsidised for the treatment of asthma.

Note The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

indacaterol 150 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5134F NP	1	5	..	59.37	31.60	Onbrez [NV]

indacaterol 300 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5137J NP	1	5	..	59.37	31.60	Onbrez [NV]

▪ SALBUTAMOL

salbutamol 100 microgram/actuation inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12109H NP	2	5	..	*25.13	26.58	[a] Zempreon CFC-Free with dose counter [AL]
			[B]0.92	*26.05	26.58	[a] Asmol CFC-Free with dose counter [AF]
			[B]4.92	*30.05	26.58	[a] Ventolin CFC-Free with dose counter [GK]

▪ SALBUTAMOL

Restricted benefit

Bronchospasm

Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8354Q NP	2	5	..	*41.45	31.60	Airomir Autohaler [IL]

▪ SALBUTAMOL

Note Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution**.**

Restricted benefit

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2000G NP	2	5	..	*24.09	25.54	[a] Salbutamol Cipla [LR]

salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2001H NP	2	5	..	*24.21	25.66	[a] Salbutamol Cipla [LR]

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11130T NP	3	5	[B]5.04	*28.11	24.52	[a] Ventolin Nebules [GK]

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13821K NP	3	5	..	*70.92	31.60	[a] pms-SALBUTAMOL [DZ]

salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11095Y NP	3	5	[B]5.01	*28.50	24.94	[a] Ventolin Nebules [GK]

▪ SALMETEROL

Restricted benefit

Asthma

Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8141L NP	‡1	5	..	30.45	31.60	Serevent Accuhaler [GK]

▪ TERBUTALINE

Authority required (STREAMLINED)

9828

Bronchospasm

Clinical criteria:

- Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist; OR
- Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

terbutaline sulfate 500 microgram/actuation powder for inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12267P NP	2	5	..	*28.13	29.58	Bricanyl Turbuhaler [AP]

Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics

▪ BECLOMETASONE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Note This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

Authority required (STREAMLINED)

11057

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 18 years or older.

beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12183F NP	‡1	5	..	38.29	31.60	Fostair [EU]

▪ BECLOMETASONE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Note This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

Authority required (STREAMLINED)

11057

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 18 years or older.

beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

13205B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	48.00	31.60	Fostair 200/6 [EU]

NP

▪ BUDESONIDE + FORMOTEROL

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Authority required (STREAMLINED)

10482

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Population criteria:

- Patient must be aged 12 years or over.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

12042T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	2	..	*42.29	31.60	[a] Rilast RAPIHALER 100/3 [XT]
		[B]4.96	*47.25	31.60	[a] Symbicort Rapihaler 100/3 [AP]

NP

▪ BUDESONIDE + FORMOTEROL

Note Patient must be aged 12 years or over.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Authority required (STREAMLINED)

10464

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

14166N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	2	..	*37.49	31.60	Bufomix Easyhaler 200/6 [OX]

NP

▪ BUDESONIDE + FORMOTEROL

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 18 years or older.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Authority required (STREAMLINED)

10464

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

12029D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	2	..	37.47	31.60	[a] BiResp Spiromax [TB]	[a] DuoResp Spiromax [EV]

NP

▪ BUDESONIDE + FORMOTEROL

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 12 years or over.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Authority required (STREAMLINED)

10464

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

12041R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	37.47	31.60	[a] Rilast TURBUHALER 200/6 [XT]
		[B]4.00	41.47	31.60	[a] Symbicort Turbuhaler 200/6 [AP]

▪ BUDESONIDE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4380

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8796Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	40.97	31.60	Symbicort Turbuhaler 100/6 [AP]

▪ BUDESONIDE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4397

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

10015D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*42.29	31.60	[a] Rilast RAPIHALER 100/3 [XT]
		[B]4.96	*47.25	31.60	[a] Symbicort Rapihaler 100/3 [AP]

budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

10024N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*40.97	31.60	Symbicort Rapihaler 50/3 [AP]

▪ BUDESONIDE + FORMOTEROL

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10538

Asthma

Clinical criteria:

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

Treatment criteria:

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

12082X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*60.91	31.60	[a] Rilast RAPIHALER 200/6 [XT]
		[B]4.96	*65.87	31.60	[a] Symbicort Rapihaler 200/6 [AP]

▪ BUDESONIDE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10538

Asthma

Clinical criteria:

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

Treatment criteria:

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

14159F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*37.49	31.60	Bufomix Easyhaler 200/6 [OX]

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

12101X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	40.97	31.60	Symbicort Turbuhaler 100/6 [AP]

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	37.47	31.60	[a] BiResp Spiromax [TB]	[a] DuoResp Spiromax [EV]

12093L						[a] Rilast TURBUHALER 200/6 [XT]
		[B]4.00	41.47	31.60	[a]	Symbicort Turbuhaler 200/6 [AP]

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12089G	‡2	5	..	*42.29	31.60	[a] Rilast RAPIHALER 100/3 [XT]
			[B]4.96	*47.25	31.60	[a] Symbicort Rapihaler 100/3 [AP]

budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12100W	‡2	5	..	*40.97	31.60	Symbicort Rapihaler 50/3 [AP]

▪ BUDESONIDE + FORMOTEROL

Note Patient must be aged 12 years or over.

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7970

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14151T	‡2	5	..	*37.49	31.60	Bufomix Easyhaler 200/6 [OX]

NP

▪ BUDESONIDE + FORMOTEROL

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 18 years or older.

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7970

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11273H	‡1	5	..	37.47	31.60	[a] BiResp Spiromax [TB]	[a] DuoResp Spiromax [EV]

NP

▪ BUDESONIDE + FORMOTEROL

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 12 years or over.

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7970

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8625Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	37.47	31.60	[a] Rilast TURBUHALER 200/6 [XT]
		[B]4.00	41.47	31.60	[a] Symbicort Turbuhaler 200/6 [AP]

▪ BUDESONIDE + FORMOTEROL

Authority required (STREAMLINED)

4404

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10121

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

10018G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*60.91	31.60	[a] Rilast RAPIHALER 200/6 [XT]
		[B]4.96	*65.87	31.60	[a] Symbicort Rapihaler 200/6 [AP]

▪ BUDESONIDE + FORMOTEROL

Note For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

Note Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

Authority required (STREAMLINED)

7979

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note Patient must be aged 18 years or older.

Note Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10121

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11301T NP	‡1	5	..	60.92	31.60	[a] BiResp Spiromax [TB]	[a] DuoResp Spiromax [EV]

budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13258T NP	2	5	..	*60.93	31.60	[a] Bufomix Easyhaler 400/12 [OX] [a] Rilast TURBUHALER 400/12 [XT]	[a] DuoResp Spiromax [EV]
			[B]4.00	*64.93	31.60	[a] Symbicort TURBUHALER 400/12 [AP]	

▪ FLUTICASONE FUROATE + VILANTEROL

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4731

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11129R NP	‡1	5	..	73.99	31.60	Breo Ellipta 200/25 [GK]

▪ FLUTICASONE FUROATE + VILANTEROL

Authority required (STREAMLINED)

4711

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10121

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11124L NP	‡1	5	..	58.49	31.60	Breo Ellipta 100/25 [GK]

▪ FLUTICASONE PROPIONATE + FORMOTEROL

Note Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4395

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2827T NP	‡1	5	..	39.28	31.60	flutiform 50/5 [MF]

fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10007Q NP	‡1	5	..	39.85	31.60	flutiform 125/5 [MF]

fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10008R NP	‡1	5	..	51.57	31.60	flutiform 250/10 [MF]

▪ FLUTICASONE PROPIONATE + SALMETEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4930

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8518H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	42.57	31.60	[a] Evocair MDI [AF]	[a] Fluticasone + Salmeterol Cipla 125/25 [LR]
					[a] Pavtide [TX]	[a] SalplusF Inhaler 125/25 [SZ]
		[B]4.00	46.57	31.60	[a] Seretide MDI 125/25 [GK]	

fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8517G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	43.93	31.60	[a] PAVTIDE MDI 50/25 [TX]
		[B]4.00	47.93	31.60	[a] Seretide MDI 50/25 [GK]

fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8430Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	43.93	31.60	[a] PAVTIDE ACCUHALER 100/50 [TX]
		[B]4.00	47.93	31.60	[a] Seretide Accuhaler 100/50 [GK]

▪ FLUTICASONE PROPIONATE + SALMETEROL

Note This product is not indicated for the initiation of treatment in asthma
Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15138

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8431R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	42.57	31.60	[a] Fluticasone Salmeterol Ciphaler 250/50 [LR]	[a] PAVTIDE ACCUHALER 250/50 [TX]
					[a] Salflumix Easyhaler 250/50 [OX]	[a] SalplusF DPI 250/50 [SZ]
		[B]4.00	46.57	31.60	[a] Seretide Accuhaler 250/50 [GK]	

▪ FLUTICASONE PROPIONATE + SALMETEROL

Authority required (STREAMLINED)

15118

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note This product is not indicated for the initiation of treatment in asthma
Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10121

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8432T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	52.87	31.60	[a] Fluticasone Salmeterol Ciphaler 500/50 [LR]	[a] PAVTIDE ACCUHALER 500/50 [TX]
					[a] Salflumix Easyhaler 500/50 [OX]	[a] SalplusF DPI 500/50 [SZ]
		[B]4.00	56.87	31.60	[a] Seretide Accuhaler 500/50 [GK]	

▪ FLUTICASONE PROPIONATE + SALMETEROL

Authority required (STREAMLINED)

4930

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10121

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8519J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	52.87	31.60	[a] Evocair MDI [AF]	[a] Fluticasone + Salmeterol Cipla 250/25 [LR]
					[a] Pavtide [TX]	[a] SalplusF Inhaler 250/25 [SZ]
		[B]4.00	56.87	31.60	[a] Seretide MDI 250/25 [GK]	

▪ INDACATEROL + MOMETASONE

Note This product is not indicated for the initiation of treatment in asthma

Note This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

11360

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12269R NP	1	5	..	37.97	31.60	Atectura Breezhaler [NV]

indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12279G NP	1	5	..	59.61	31.60	Atectura Breezhaler [NV]

indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12289T NP	1	5	..	43.78	31.60	Atectura Breezhaler [NV]

Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids

▪ ACLIDINIUM + FORMOTEROL

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10565C NP	‡1	5	..	82.25	31.60	Brimica Genuair [FK]

▪ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

12349

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12468F NP	‡1	5	..	81.75	31.60	Trimbow [EU]

▪ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note This product is not indicated for the initiation of treatment in asthma

Note This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

12603

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13200R NP	‡1	5	..	79.93	31.60	Trimbow [EU]

▪ BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

12349

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12672Y NP	‡1	5	..	78.97	31.60	Breztri Aerosphere [AP]

▪ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

12349

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11379X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	89.13	31.60	Trelegy Ellipta 100/62.5/25 [GK]

▪ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

12603

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

12917W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	93.04	31.60	Trelegy Ellipta 200/62.5/25 [GK]

▪ INDACATEROL + GLYCOPYRRONIUM

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

10156M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	86.99	31.60	ultibro breezhaler 110/50 [NV]

▪ INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

12603

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules

12295D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	89.05	31.60	Enerzair Breezhaler [NV]

indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules

12298G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	73.22	31.60	Enerzair Breezhaler [NV]

▪ TIOTROPIUM + OLODATEROL

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10557P NP	‡1	5	..	75.04	31.60	Spiolto Respimat [BY]

▪ UMECLIDINIUM + VILANTEROL

Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.
Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note A SAMA includes ipratropium
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)
7798
Chronic obstructive pulmonary disease (COPD)
Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10188F NP	‡1	5	..	90.85	31.60	Anoro Ellipta 62.5/25 [GK]

OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

Glucocorticoids

▪ BECLOMETASONE

beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8406K NP	‡1	5	..	20.53	21.98	Qvar 50 [IL]

beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8407L NP	‡1	5	..	28.32	29.77	Qvar 100 [IL]

▪ BECLOMETASONE

Restricted benefit
Asthma
Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8409N NP	‡1	5	..	31.43	31.60	Qvar 100 Autohaler [IL]

beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8408M NP	‡1	5	..	25.24	26.69	Qvar 50 Autohaler [IL]

▪ BUDESONIDE

budesonide 100 microgram/actuation powder for inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2070Y NP	‡1	5	..	22.76	24.21	Pulmicort Turbuhaler [AP]

budesonide 200 microgram/actuation powder for inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2071B NP	‡1	5	..	30.14	31.59	Pulmicort Turbuhaler [AP]

budesonide 400 microgram/actuation powder for inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2072C NP	‡1	5	..	35.53	31.60	Pulmicort Turbuhaler [AP]

▪ BUDESONIDE

Authority required (STREAMLINED)

6340

Severe chronic asthma

Clinical criteria:

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2066R NP	‡1	5	..	37.52	31.60	Pulmicort Respules [AP]

budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2065Q NP	‡1	5	..	35.11	31.60	Pulmicort Respules [AP]

▪ CICLESONIDE

ciclesonide 160 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8854B NP	‡1	5	..	33.24	31.60	Alvesco 160 [EU]

ciclesonide 80 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8853Y NP	‡1	5	..	24.30	25.75	Alvesco 80 [EU]

▪ FLUTICASONE FUROATE

fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11719T NP	‡1	5	..	30.29	31.60	Arnuity Ellipta [GK]

fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11729H NP	‡1	5	..	44.43	31.60	Arnuity Ellipta [GK]

▪ FLUTICASONE PROPIONATE

fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8147T NP	‡1	5	..	19.32	20.77	[a] Axotide Junior Accuhaler [TX]
			[B]4.00	23.32	20.77	[a] Flixotide Junior Accuhaler [GK]

fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8148W NP	‡1	5	..	26.78	28.23	[a] Axotide Accuhaler [TX]
			[B]4.00	30.78	28.23	[a] Flixotide Accuhaler [GK]

fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8149X NP	‡1	1	..	37.97	31.60	Flixotide Accuhaler [GK]

fluticasone propionate 125 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8345F NP	‡1	5	..	26.78	28.23	[a] Axotide [TX]	[a] Fluticasone Cipla Inhaler [LR]
			[B]3.00	29.78	28.23	[a] Flixotide [GK]	

fluticasone propionate 250 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8346G NP	‡1	1	..	37.97	31.60	[a] Axotide [TX]	[a] Fluticasone Cipla Inhaler [LR]
			[B]3.00	40.97	31.60	[a] Flixotide [GK]	

▪ FLUTICASONE PROPIONATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14180

Asthma

Clinical criteria:

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.

fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8516F NP	‡1	5	..	20.87	22.32	[a] Axotide Junior [TX]
			[B]4.00	24.87	22.32	[a] Flixotide Junior [GK]

Anticholinergics

▪ ACLIDINIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10124W NP	‡1	5	..	61.79	31.60	Bretaris Genuair [FK]

▪ GLYCOPYRRONIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

glycopyrronium 50 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10059K NP	1	5	..	59.37	31.60	seebri breezhaler [NV]

▪ IPRATROPIUM

ipratropium bromide monohydrate 21 microgram/actuation inhalation, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8671J NP	2	5	..	*34.61	31.60	Atrovent [BY]

▪ IPRATROPIUM

Restricted benefit

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules

1542E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*27.25	28.70	[a] Aeron 250 [AL]	[a] Ipratrin [AF]
		[B]0.44	*27.69	28.70	[a] Atrovent [BY]	

ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules

8238N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*29.77	31.22	[a] Aeron 500 [AL]	[a] Ipratrin Adult [AF]
		[B]0.44	*30.21	31.22	[a] Atrovent Adult [BY]	

▪ TIOTROPIUM

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Restricted benefit

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

11043F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	44.45	31.60	Spiriva Respimat [BY]

▪ TIOTROPIUM

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

8606

Severe asthma

Treatment criteria:

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

Clinical criteria:

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11629C NP	‡1	5	..	44.45	31.60	Spiriva Respimat [BY]

▪ TIOTROPIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA
Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
Note A SAMA includes ipratropium
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease
Treatment Phase: Long-term maintenance treatment

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10509D NP	‡1	5	..	44.45	31.60	Spiriva Respimat [BY]

▪ TIOTROPIUM

Note Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.
Note The treatment must not be used in combination with a LAMA/LABA or SAMA
Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
Note A SAMA includes ipratropium
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

tiotropium 18 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8626B NP	1	5	..	44.45	31.60	[a] Spiriva [BY]

tiotropium 13 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11892X NP	1	5	..	39.57	31.60	[a] Braltus [TB]

▪ UMECLIDINIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA
Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
Note A SAMA includes ipratropium
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10187E NP	‡1	5	..	61.79	31.60	Incruse Ellipta [GK]

ADRENERGICS FOR SYSTEMIC USE

Alpha- and beta-adrenoreceptor agonists

▪ ADRENALINE (EPINEPHRINE)

Note Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1016L NP	1	1	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5004J DP	1	..	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

▪ ADRENALINE (EPINEPHRINE)

Caution Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note No increase in the maximum quantity or number of units may be authorised.

Note No applications for repeats will be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug.

adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8697R NP	2	..	..	*160.17	31.60	[a] Adrenaline Jr Viatris [AF] [a] EpiPen Jr. [AL]	[a] Anapen Junior 150 [XT]

adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8698T NP	2	..	..	*160.17	31.60	[a] Adrenaline Viatris [AF] [a] EpiPen [AL]	[a] Anapen 300 [XT]

adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12655C NP	2	..	..	*160.17	31.60	Anapen 500 [XT]

Selective beta-2-adrenoreceptor agonists

▪ SALBUTAMOL

salbutamol 2 mg/5 mL oral liquid, 150 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1103C NP	2	5	..	*27.19	28.64	Ventolin [GK]

▪ TERBUTALINE

terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1034K NP	1	..	..	26.74	28.19	Bricanyl [AP]

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Xanthines

▪ THEOPHYLLINE

Caution Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

theophylline 200 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8230E NP	1	5	..	18.02	19.47	Nuelin-SR 200 [IL]

theophylline 250 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2634P NP	1	5	..	18.85	20.30	Nuelin-SR 250 [IL]

theophylline 300 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8231F NP	1	5	..	19.91	21.36	Nuelin-SR 300 [IL]

theophylline 133.3 mg/25 mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2614N NP	‡1	5	..	18.32	19.77	Nuelin [IL]

Leukotriene receptor antagonists

▪ MONTELUKAST

Note This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Note This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6666

Asthma

Treatment Phase: First-line prevention

Population criteria:

- Patient must be aged 2 to 5 years inclusive.

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

montelukast 4 mg chewable tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8627C NP	1	5	..	17.96	19.41	[a] MONTELAIR 4 [RF] [a] Montelukast Lupin [HQ] [a] Montelukast Sandoz 4 [SZ]	[a] Montelukast APOTEX [GX] [a] Montelukast Mylan [AF]

▪ MONTELUKAST

Note This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6674

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

Authority required (STREAMLINED)

7781

Asthma

Treatment Phase: Prevention of condition

Clinical criteria:

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

montelukast 5 mg chewable tablet, 28

8628D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.87	19.32	[a] MONTELAIR 5 [RF] [a] Montelukast Lupin [HQ] [a] Montelukast Sandoz 5 [SZ]	[a] Montelukast APOTEX [GX] [a] Montelukast Mylan [AF]

ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

Phenothiazine derivatives

PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

1948M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*36.65	31.60	DBL Promethazine Hydrochloride [PF]

SENSORY ORGANS

OPHTHALMOLOGICALS

ANTIINFECTIVES

Antibiotics

AZITHROMYCIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	#28.96	30.83	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	17.85	19.30	[a] APO-Azithromycin [TX] [a] Azithromycin Sandoz [SZ] [a] ZITHRO [RW]	[a] Azithromycin Mylan [AF] [a] Azithromycin Viatris [AL] [a] Zithromax [PF]

CHLORAMPHENICOL

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

chloramphenicol 0.5% eye drops, 10 mL

11112W (OP) (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	17.57	19.02	Chlorsig [AS]

TOBRAMYCIN

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

tobramycin 0.3% eye drops, 5 mL

5569D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	24.08	25.53	Tobrex [NV]

OP

tobramycin 0.3% eye ointment, 3.5 g

5570E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	26.64	28.09	Tobrex [NV]

OP

▪ TOBRAMYCIN

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

tobramycin 0.3% eye drops, 5 mL

2328M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	24.08	25.53	Tobrex [NV]

tobramycin 0.3% eye ointment, 3.5 g

2329N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	26.64	28.09	Tobrex [NV]

Antivirals

▪ ACICLOVIR

Restricted benefit

Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g

5501M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	..	..	28.60	30.05	[a] ViruPOS [AE]	[a] XOROX [IX]

OP

▪ ACICLOVIR

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g

1002R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	..	..	28.60	30.05	[a] ViruPOS [AE]	[a] XOROX [IX]

NP

Fluoroquinolones

▪ CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ciprofloxacin 0.3% eye drops, 5 mL

1217C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*32.65	31.60	[a] CiloQuin [NM]
		[B]4.36	*37.01	31.60	[a] Ciloxan [NV]

▪ CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ciprofloxacin 0.3% eye drops, 5 mL

5564W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*32.65	31.60	[a] CiloQuin [NM]
		[B]4.36	*37.01	31.60	[a] Ciloxan [NV]

OP

▪ OFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ofloxacin 0.3% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5567B OP	2	..	..	*29.33	30.78	Ocuflox [VE]

▪ OFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ofloxacin 0.3% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8383F	2	..	..	*29.33	30.78	Ocuflox [VE]

ANTIINFLAMMATORY AGENTS

Corticosteroids, plain

▪ DEXAMETHASONE

dexamethasone 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1288T NP	‡1	2	..	23.59	25.04	Maxidex [NV]

▪ DEXAMETHASONE

Authority required

Non-infectious posterior segment uveitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema, **AND**
- Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated.

dexamethasone 700 microgram implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11317P	1	..	..	1211.74	31.60	Ozurdex [VE]

▪ DEXAMETHASONE

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

dexamethasone 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5565X OP	‡1	..	..	23.59	25.04	Maxidex [NV]

▪ DEXAMETHASONE

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

dexamethasone 700 microgram implant, 1

10943Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1211.74	31.60	Ozurdex [VE]

▪ DEXAMETHASONE

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13428

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

dexamethasone 700 microgram implant, 1

13168C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1211.74	31.60	Ozurdex [VE]

▪ DEXAMETHASONE

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

dexamethasone 700 microgram implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11469P	1	1	..	1211.74	31.60	Ozurdex [VE]

▪ DEXAMETHASONE

Note Special Pricing Arrangements apply.
Note No increase in the maximum number of repeats may be authorised.
Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13387

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority required (STREAMLINED)

13336

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

dexamethasone 700 microgram implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13142Q	1	1	..	1211.74	31.60	Ozurdex [VE]

▪ FLUOROMETHOLONE

fluorometholone 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1204J NP	‡1	5	..	16.62	18.07	FML Liquifilm [VE]

▪ FLUOROMETHOLONE

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

fluorometholone 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5513E OP	‡1	..	..	16.62	18.07	FML Liquifilm [VE]

▪ HYDROCORTISONE ACETATE

hydrocortisone acetate 1% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2441L NP	‡1	..	..	18.94	20.39	Hycor [AS]

▪ HYDROCORTISONE ACETATE

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

hydrocortisone acetate 1% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5516H OP	‡1	..	..	18.94	20.39	Hycor [AS]

Corticosteroids and mydriatics in combination

▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

Restricted benefit

Severe eye inflammation

Clinical criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11908R	‡1	..	..	24.12	25.57	Prednefrin Forte [VE]

▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

Restricted benefit

Corneal grafts

Restricted benefit

Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3112T NP	‡1	2	..	24.12	25.57	Prednefrin Forte [VE]

▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5568C OP	‡1	..	..	24.12	25.57	Prednefrin Forte [VE]

ANTIGLAUCOMA PREPARATIONS AND MIOTICS

Sympathomimetics in glaucoma therapy

▪ BRIMONIDINE

brimonidine tartrate 0.15% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5298W	‡1	5	..	21.16	22.61	Alphagan P 1.5 [VE]

brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8351M	‡1	5	..	21.63	23.08	[a] Enidin [VB]
			[B]0.98	22.61	23.08	[a] Alphagan [VE]

▪ BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

brimonidine tartrate 0.15% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5563T OP	‡1	5	..	21.16	22.61	Alphagan P 1.5 [VE]

brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5534G OP	‡1	5	..	21.63	23.08	[a] Enidin [VB]
			[B]0.98	22.61	23.08	[a] Alphagan [VE]

▪ BRIMONIDINE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8826M	‡1	5	..	26.18	27.63	Combigan [VE]

▪ BRIMONIDINE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5535H OP	‡1	5	..	26.18	27.63	Combigan [VE]

Parasympathomimetics

▪ PILOCARPINE

pilocarpine hydrochloride 1% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2595N	‡1	5	..	18.81	20.26	Isopto Carpine [NV]

pilocarpine hydrochloride 2% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2596P	‡1	5	..	19.86	21.31	Isopto Carpine [NV]

pilocarpine hydrochloride 4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2598R	‡1	5	..	22.34	23.79	Isopto Carpine [NV]

▪ PILOCARPINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

pilocarpine hydrochloride 1% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5536J OP	‡1	5	..	18.81	20.26	Isopto Carpine [NV]

pilocarpine hydrochloride 2% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5537K OP	‡1	5	..	19.86	21.31	Isopto Carpine [NV]

pilocarpine hydrochloride 4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5538L OP	‡1	5	..	22.34	23.79	Isopto Carpine [NV]

Carbonic anhydrase inhibitors

▪ ACETAZOLAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

acetazolamide 250 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1004W NP	1	3	..	23.98	25.43	Diamox [RW]

▪ BRINZOLAMIDE

brinzolamide 1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8483L	‡1	5	..	23.20	24.65	[a] BrinzoQuin [NM]
			[B]3.27	26.47	24.65	[a] Azopt [NV]

▪ BRINZOLAMIDE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

brinzolamide 1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5540N OP	‡1	5	..	23.20	24.65	[a] BrinzoQuin [NM]
			[B]3.27	26.47	24.65	[a] Azopt [NV]

▪ BRINZOLAMIDE + BRIMONIDINE

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10536M	‡1	5	..	24.80	26.25	Simbrinza 1%/0.2% [NV]

▪ BRINZOLAMIDE + BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10547D OP	‡1	5	..	24.80	26.25	Simbrinza 1%/0.2% [NV]

▪ BRINZOLAMIDE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3438Y	‡1	5	..	26.67	28.12	Azarga [NV]

▪ BRINZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5562R OP	‡1	5	..	26.67	28.12	Azarga [NV]

▪ DORZOLAMIDE

dorzolamide 2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8488R	‡1	5	..	18.80	20.25	[a] Trusamide [AF]	[a] Trusopt [MF]

▪ DORZOLAMIDE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

dorzolamide 2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5541P OP	‡1	5	..	18.80	20.25	[a] Trusamide [AF]	[a] Trusopt [MF]

▪ DORZOLAMIDE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

8567X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	21.99	23.44	[a] Cosdor [AF]	[a] Vizo-PF Dorzolatim [AE]
		[B]0.80	22.79	23.44	[a] Cosopt [MF]	

▪ DORZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

5542Q

OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	21.99	23.44	[a] Cosdor [AF]	[a] Vizo-PF Dorzolatim [AE]
		[B]0.80	22.79	23.44	[a] Cosopt [MF]	

Beta blocking agents

▪ BETAXOLOL

betaxolol 0.5% eye drops, 5 mL

2825Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	20.72	22.17	[a] BetoQuin [NM]
		[B]4.76	25.48	22.17	[a] Betoptic [NV]

▪ BETAXOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

betaxolol 0.5% eye drops, 5 mL

5544T

OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	20.72	22.17	[a] BetoQuin [NM]
		[B]4.76	25.48	22.17	[a] Betoptic [NV]

▪ TIMOLOL

timolol 0.5% eye drops, 2.5 mL

1926J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	18.64	20.09	Timoptol XE [MF]

timolol 0.5% eye drops, 5 mL

1279H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	18.59	20.04	Timoptol [MF]

▪ TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

timolol 0.5% eye drops, 2.5 mL

5550D

OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	18.64	20.09	Timoptol XE [MF]

timolol 0.5% eye drops, 5 mL

5548B

OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	18.59	20.04	Timoptol [MF]

Prostaglandin analogues

▪ BIMATOPROST

bimatoprost 0.03% eye drops, 3 mL

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	33.19	31.60	[a] Bimatoprost Sandoz [SZ]	[a] Bimprozt [TY]

8620Q						[a] Bimtop [AF]	[a] Lumigan [VE]

bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10046R	‡1	5	..	30.03	31.48	Lumigan PF [VE]

▪ BIMATOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

bimatoprost 0.03% eye drops, 3 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5551E	‡1	5	..	33.19	31.60	[a] Bimatoprost Sandoz [SZ]	[a] Bimprozt [TY]
OP						[a] Bimtop [AF]	[a] Lumigan [VE]

bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10053D	‡1	5	..	30.03	31.48	Lumigan PF [VE]
OP						

▪ BIMATOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10107Y	‡1	5	..	34.78	31.60	GANfort PF 0.3/5 [VE]

▪ BIMATOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9464D	‡1	5	..	37.05	31.60	Ganfort 0.3/5 [VE]

▪ BIMATOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5558M	‡1	5	..	37.05	31.60	Ganfort 0.3/5 [VE]
OP						

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10108B	‡1	5	..	34.78	31.60	GANfort PF 0.3/5 [VE]
OP						

▪ LATANOPROST

latanoprost 0.005% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8243W	‡1	5	..	17.87	19.32	[a] APO-Latanoprost [TX]	[a] Latanoprost Sandoz [SZ]
						[a] Xalaprost [AF]	[a] Xalatan [AS]

▪ LATANOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

latanoprost 0.005% eye drops, 2.5 mL

5552F (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	17.87	19.32	[a] APO-Latanoprost [TX] [a] Xalaprost [AF]	[a] Latanoprost Sandoz [SZ] [a] Xalatan [AS]

▪ LATANOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

8895E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	21.61	23.06	[a] APO-Latanoprost/Timolol 0.05/5 [TX] [a] Xalamol 50/5 [AF]	[a] Xalacom [AS]

▪ LATANOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

5553G (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	21.61	23.06	[a] APO-Latanoprost/Timolol 0.05/5 [TX] [a] Xalamol 50/5 [AF]	[a] Xalacom [AS]

▪ TAFLUPROST

tafluprost 0.0015% eye drops, 30 x 0.3 mL ampoules

2755B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	34.96	31.60	Saflutan [MF]

▪ TAFLUPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

tafluprost 0.0015% eye drops, 30 x 0.3 mL ampoules

2748P (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	34.96	31.60	Saflutan [MF]

▪ TRAVOPROST

travoprost 0.004% eye drops, 2.5 mL

8597L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	33.19	31.60	Travatan [NV]

▪ TRAVOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

travoprost 0.004% eye drops, 2.5 mL

5554H (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	33.19	31.60	Travatan [NV]

▪ TRAVOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9057Q	‡1	5	..	36.14	31.60	Duotrav [NV]

▪ TRAVOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5555J (OP)	‡1	5	..	36.14	31.60	Duotrav [NV]

MYDRIATICS AND CYCLOPLEGICS

Anticholinergics

▪ ATROPINE SULFATE

atropine sulfate monohydrate 1% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1093M (NP)	‡1	2	..	24.31	25.76	Atropt [AS]

OCULAR VASCULAR DISORDER AGENTS

Antineovascularisation agents

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

10505X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

12153P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

12131L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

12141B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

2168D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

12152N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13392

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

13151E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

13139M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13406

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

13146X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

13167B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13402

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

13164W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

13150D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

11991D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

12132M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13387

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority required (STREAMLINED)

13336

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

13138L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

13141P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	890.64	31.60	[a] Eylea [BN]

▪ BROLUCIZUMAB

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

brolucizumab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

12667Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	995.38	31.60	Beovu [NV]

▪ FARICIMAB

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

13177M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	934.08	31.60	Vabysmo [RO]

▪ FARICIMAB

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

13183W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	934.08	31.60	Vabysmo [RO]

▪ FARICIMAB

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13406

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

13195L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	934.08	31.60	Vabysmo [RO]

▪ FARICIMAB

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13402

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

13198P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	934.08	31.60	Vabysmo [RO]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

1382R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

10138N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**

- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

10373Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

10374B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13402

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

13165X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

13134G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13406

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

13137K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

13157L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

11471R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

11480F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

11981N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

11975G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13392

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

Authority required (STREAMLINED)

13340

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13156K	1	2	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13143R	1	2	..	786.36	31.60	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

13387

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority required (STREAMLINED)

13336

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13149C	1	2	..	786.36	31.60	[a] Lucentis [NV]

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13166Y	1	2	..	786.36	31.60	[a] Lucentis [NV]

OTHER OPHTHALMOLOGICALS

Other ophthalmologicals

▪ CARBOMER-980

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5503P	‡1	5	..	16.99	18.44	[a] Optifresh eye gel [PP]	[a] PAA [UL]
OP			[B]3.67	20.66	18.44	[a] Viscotears [UO]	

carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8384G	‡1	5	..	16.99	18.44	[a] Optifresh eye gel [PP]	[a] PAA [UL]
NP			[B]3.67	20.66	18.44	[a] Viscotears [UO]	

▪ CARBOMER-980

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-980 0.2% eye drops, 30 x 600 mg ampoules

5504Q (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*31.14	31.60	Viscotears Gel PF [UO]

carbomer-980 0.2% eye drops, 30 x 600 mg ampoules

8578L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*31.14	31.60	Viscotears Gel PF [UO]

▪ CARBOMER-980

Note No applications for increased maximum quantities will be authorised.
Note No applications for repeats will be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carbomer-980 0.2% eye gel, 10 g

9210R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	11	..	16.99	18.44	[a] Optifresh eye gel [PP]	[a] PAA [UL]
		[B]3.67	20.66	18.44	[a] Viscotears [UO]	

▪ CARMELLOSE SODIUM

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 1% eye drops, 15 mL

5508X (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	16.61	18.06	Refresh Liquigel [VE]

carmellose sodium 0.5% eye drops, 15 mL

5507W (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	16.61	18.06	Refresh Tears Plus [VE]

▪ CARMELLOSE SODIUM

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 1% eye drops, 15 mL

8593G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	16.61	18.06	Refresh Liquigel [VE]

carmellose sodium 0.5% eye drops, 15 mL

8548X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	16.61	18.06	Refresh Tears Plus [VE]

▪ CARMELLOSE SODIUM

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules

2324H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*27.15	28.60	Celluvisc [VE]

carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules

5505R (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*27.15	28.60	Celluvisc [VE]

carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules

2338C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*27.15	28.60	Cellufresh [VE]

carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5506T OP	3	5	..	*27.15	28.60	Cellufresh [VE]

▪ CARMELLOSE SODIUM

Note The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 0.5% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11852T NP	‡1	5	..	25.01	26.46	Evolve Carmellose [CX]

carmellose sodium 0.5% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11853W OP	‡1	5	..	25.01	26.46	Evolve Carmellose [CX]

▪ CARMELLOSE SODIUM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carmellose sodium 1% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9212W	‡1	11	..	16.61	18.06	Refresh Liquigel [VE]

carmellose sodium 0.5% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9211T	‡1	11	..	16.61	18.06	Refresh Tears Plus [VE]

▪ CARMELLOSE SODIUM + GLYCEROL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5556K OP	‡1	3	..	16.61	18.06	Optive [VE]

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9355J NP	‡1	3	..	16.61	18.06	Optive [VE]

▪ CARMELLOSE SODIUM + GLYCEROL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9356K	‡1	7	..	16.61	18.06	Optive [VE]

▪ CICLOSPORIN

Caution It is recommended that the potential for immunosuppression with long term use of this drug be clinically reviewed after at least 24 months of treatment, if not already reviewed.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Chronic severe dry eye disease with keratitis

Treatment Phase: Initial treatment for up to the first 180 days of treatment

Clinical criteria:

- Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber, **AND**
- Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation, **AND**
- The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute, **AND**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines, **AND**
- Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment.

Population criteria:

- Patient must be at least 18 years of age.

Prescribing instruction:

State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).

Note The Oxford scale, modified Oxford scale and Ocular Surface Disease Index (OSDI) were relied upon in the submission supporting initial PBS listing.

The Oxford scale uses a chart system consisting of a series of panels, labelled A to E in order of increasing severity. In each chart, staining is represented by dots. To grade staining, comparisons are made between the panels and the appearance of staining on the exposed interpalpebral conjunctiva and cornea of the patient. The details of the chart are presented in Figure 1 and, in a simplified form in Figure 4 (where the criteria, dot count and log columns are not displayed), in the following literature article: Bron A, Evans V, Smith, J. Grading of corneal and conjunctival staining in the context of other dry eye tests. Cornea. 2003;22(7):640-650.

The modified Oxford scale is as above, but with the first grade depiction (Grade 0), termed 'Grade 0.5'.

A list of equivalent scales to the Oxford scale is not provided. Prescribers should be satisfied that a scale other than the Oxford scale, if used, is equivalent to the Oxford scale.

The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire created by the Outcomes Research Group at Allergan Inc, Irvine, CA, USA, to assess dry eye symptoms and the effects on vision-related function.

The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a 0 to 4 scale with 0 corresponding to 'none of the time' and 4 corresponding to 'all of the time'. A final score is calculated which ranges from 0 to 100 with scores 0 to 12 representing normal, 13 to 22 representing mild dry eye disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease.

The OSDI questionnaire asks the following:

Presence of ocular symptoms - Have you experienced any of the following during the last week?

1. Eyes that are sensitive to light
2. Eyes that feel gritty
3. Painful or sore eyes
4. Blurred vision
5. Poor vision

Impact on daily activities - Have you had problems with your eyes limited you in performing any of the following during the last week?

1. Reading
2. Driving at night
3. Working with a computer or bank machine (ATM)
4. Watching TV

Environmental factors - Have your eyes felt uncomfortable in any of the following situations during the last week?

1. Windy conditions
2. Places or areas with low humidity (very dry)
3. Areas that are airconditioned

Rate responses on a scale of 0 to 4; 0 = none of the time, 1 = some of the time, 2 = half of the time, 3 = most of the time, and 4 = all of the time.

Further information on this index is in the following literature article: Walt J, Rowe M, Stern K. Evaluating the functional impact of dry eye: the Ocular Surface Disease Index. Drug Information Journal. 1997;31:1436

The 'Dry Eye OSDI 'Questionnaire' app developed by Allergan Inc is available to download for iPhone.

Note If the maximum number of repeats stated in this listing is not requested in this application, further supplies can be obtained through this treatment phase listing to continue treatment for up to the first 180 days of treatment, but the OSDI score and CFS grade need not be re-stated. Alternatively, treatment may be continued under the 'Continuing treatment' phase listing, provided the patient meets all eligibility criteria specified in that treatment phase listing.

Authority required

Chronic severe dry eye disease with keratitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**

- The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application, **AND**
- The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.

Prescribing instructions:

State in the first continuing treatment authority application for this drug:

(i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application).

State in all continuing treatment authority applications:

(ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).

ciclosporin 0.09% eye drops, 60 x 0.25 mL ampoules

13284E (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	83.35	31.60	Cequa [RA]

ciclosporin 0.1% eye drops, 30 x 0.3 mL ampoules

12663L (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	83.35	31.60	Ikervis [CS]

▪ DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

1509K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	17.37	18.82	[a] Poly-Tears [IQ]
		[B]3.85	21.22	18.82	[a] Tears Naturale [AQ]

▪ DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

5520M (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	17.37	18.82	[a] Poly-Tears [IQ]
		[B]3.85	21.22	18.82	[a] Tears Naturale [AQ]

▪ DEXTRAN-70 + HYPROMELLOSE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

9216C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	11	..	17.37	18.82	[a] Poly-Tears [IQ]
		[B]3.85	21.22	18.82	[a] Tears Naturale [AQ]

▪ HYALURONATE SODIUM

Note The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

Authority required (STREAMLINED)

4105

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

hyaluronate sodium 0.1% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2181T NP	‡1	5	..	34.81	31.60	Hylo-Fresh [AE]

hyaluronate sodium 0.1% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2184Y OP	‡1	5	..	34.81	31.60	Hylo-Fresh [AE]

hyaluronate sodium 0.2% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2171G OP	‡1	5	..	34.81	31.60	Hylo-Forte [AE]

hyaluronate sodium 0.2% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2253N NP	‡1	5	..	34.81	31.60	Hylo-Forte [AE]

▪ HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.5% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2956N NP	‡1	5	..	17.37	18.82	Methopt [AF]

hypromellose 0.3% w/w eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11625W NP	‡1	5	..	16.37	17.82	[a] In a Wink Moisturising [IQ]	[a] Revive Tears [PP]
			[B]3.41	19.78	17.82	[a] Genteal [AQ]	

▪ HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.5% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5517J OP	‡1	5	..	17.37	18.82	Methopt [AF]

hypromellose 0.3% w/w eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11634H OP	‡1	5	..	16.37	17.82	[a] In a Wink Moisturising [IQ]	[a] Revive Tears [PP]
			[B]3.41	19.78	17.82	[a] Genteal [AQ]	

▪ HYPROMELLOSE

Note The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

hypromellose 0.3% w/v eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11842G NP	‡1	5	..	25.01	26.46	Evolve Hypromellose [CX]

hypromellose 0.3% w/v eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11849P OP	‡1	5	..	25.01	26.46	Evolve Hypromellose [CX]

▪ HYPROMELLOSE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

hypromellose 0.5% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9214Y	‡1	11	..	17.37	18.82	Methopt [AF]

hypromellose 0.3% w/w eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11643T	‡1	11	..	16.37	17.82	[a] In a Wink Moisturising [IQ]	[a] Revive Tears [PP]
			[B]3.41	19.78	17.82	[a] Genteal [AQ]	

▪ HYPROMELLOSE + CARBOMER-980

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5519L (OP)	‡1	5	..	17.37	18.82	[a] HPMC PAA [IQ]
			[B]4.65	22.02	18.82	[a] Genteal gel [AQ]

▪ HYPROMELLOSE + CARBOMER-980

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8564R (NP)	‡1	5	..	17.37	18.82	[a] HPMC PAA [IQ]
			[B]4.65	22.02	18.82	[a] Genteal gel [AQ]

▪ HYPROMELLOSE + CARBOMER-980

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9215B	‡1	11	..	17.37	18.82	[a] HPMC PAA [IQ]
			[B]4.65	22.02	18.82	[a] Genteal gel [AQ]

▪ LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE

Note The in-use shelf life of Cationorm is 3 months from the date of opening.

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12612T (OP) (NP)	‡1	5	..	35.80	31.60	Cationorm [CS]

▪ PARAFFIN

paraffin 1 g/g eye ointment, 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1754H (NP)	2	5	..	*21.17	22.62	Poly Visc [IQ]

paraffin 1 g/g eye ointment, 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5523Q (OP)	2	5	..	*21.17	22.62	Poly Visc [IQ]

paraffin 1 g/g eye ointment, 2 x 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1750D (NP)	‡1	5	..	20.84	22.29	Poly Visc [IQ]
			[B]1.09	21.93	22.29	Refresh Night Time [VE]

paraffin 1 g/g eye ointment, 2 x 3.5 g

5522P OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	20.84	22.29	Poly Visc [IQ]
		[B]1.09	21.93	22.29	Refresh Night Time [VE]

▪ PARAFFIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 2 x 3.5 g

9218E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	11	..	20.84	22.29	Poly Visc [IQ]
		[B]1.09	21.93	22.29	Refresh Night Time [VE]

▪ PARAFFIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 3.5 g

9217D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	11	..	*21.17	22.62	Poly Visc [IQ]

▪ PERFLUOROHEXYLOCTANE

Note The in-use shelf life of Novatears is 6 months from the date of opening.

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

perfluorohexyloctane 100% eye drops, 3 mL

11439C OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	33.89	31.60	Novatears [AE]

perfluorohexyloctane 100% eye drops, 3 mL

11446K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	33.89	31.60	Novatears [AE]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

5524R OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	16.18	17.63	[a] Optix [PP]	[a] Systane [AQ]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

8676P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	16.18	17.63	[a] Optix [PP]	[a] Systane [AQ]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses

13100L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*34.41	31.60	Systane [AQ]

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses

13113E OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*34.41	31.60	Systane [AQ]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

9219F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	11	..	16.18	17.63	[a] Optix [PP]	[a] Systane [AQ]

▪ SOY LECITHIN + TOCOPHEROL + VITAMIN A

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

5545W OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*35.51	31.60	tearsagain [RB]

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

9448G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*35.51	31.60	tearsagain [RB]

▪ OTOLOGICALS

ANTIINFECTIVES

Antiinfectives

▪ CIPROFLOXACIN

Authority required

Chronic suppurative otitis media

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

Authority required

Chronic suppurative otitis media

Population criteria:

- Patient must be less than 18 years of age.

Clinical criteria:

- Patient must have perforation of the tympanic membrane.

Authority required

Chronic suppurative otitis media

Population criteria:

- Patient must be less than 18 years of age.

Clinical criteria:

- Patient must have a grommet in situ.

ciprofloxacin 0.3% ear drops, 5 mL

2480M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	38.62	31.60	Ciloxan [NV]

CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

Corticosteroids and antiinfectives in combination

▪ FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE

framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL

2781J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	17.22	18.67	[a] Otodex [AV]
		[B]2.25	19.47	18.67	[a] Sofradex [SW]

▪ TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN

triamcinolone acetonide 0.09% + neomycin 0.225% + gramicidin 0.0225% + nystatin 90 000 units/mL ear drops, 7.5 mL

2971J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	17.65	19.10	[a] Otocomb Otic [LN]
		[B]1.58	19.23	19.10	[a] Kenacomb Otic [AS]

triamcinolone acetonide 0.1% + neomycin 0.25% + gramicidin 0.025% + nystatin 100 000 units/g ointment, 5 g

2974M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	16.37	17.82	[a] Otocomb Otic [LN]
		[B]2.66	19.03	17.82	[a] Kenacomb Otic [AS]

▪ OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

ANTIINFECTIVES

Antiinfectives

▪ FRAMYCETIN SULFATE

framycetin sulfate 0.5% eye/ear drops, 8 mL

1440T (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	16.72	18.17	Soframycin [SW]

framycetin sulfate 0.5% eye/ear drops, 8 mL

5557L (OP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	16.72	18.17	Soframycin [SW]

▪ VARIOUS

▪ ALLERGENS

ALLERGENS

Allergen extracts

▪ HONEY BEE VENOM

honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2886X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	183.68	31.60	Albey Bee Venom [DE]

honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10621B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	297.90	31.60	Hymenoptera Honey Bee Venom [DE]

▪ PAPER WASP VENOM

Note Paper wasp venom is not European wasp venom

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2918N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	183.68	31.60	Albey Paper Wasp Venom [DE]

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10620Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	348.16	31.60	Hymenoptera Paper Wasp Venom [DE]

▪ YELLOW JACKET VENOM

yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2883R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	183.68	31.60	Albey Yellow Jacket Venom [DE]

yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10622C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	402.89	31.60	Hymenoptera Yellow Jacket Venom [DE]

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Antidotes

▪ NALOXONE

naloxone hydrochloride 1 mg/mL injection, 2 mL syringe

11077B (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	37.43	31.60	Prenoxad [FF]

naloxone hydrochloride 1 mg/mL injection, 2 mL syringe

11078C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	37.43	31.60	Prenoxad [FF]

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10783M (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	35.57	31.60	[a] Naloxone Hydrochloride (DBL) [PF] [a] NALOXONE SXP [XN]	[a] Naloxone Juno [JU]

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10787R (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	35.57	31.60	[a] Naloxone Hydrochloride (DBL) [PF] [a] NALOXONE SXP [XN]	[a] Naloxone Juno [JU]

▪ NALOXONE

Note Pharmaceutical Benefits that have the form naloxone 1.8 mg mg/actuation nasal spray, 2 x 1 actuation are equivalent for the purpose of substitution in case of a shortage.

naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

11816X (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	50.40	31.60	[a] Nyxoid [MF]

naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

11817Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	50.40	31.60	[a] Nyxoid [MF]

naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

13617Q (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	110.23	31.60	[a] Nyxoid (UK) [QY]

naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

13621X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	110.23	31.60	[a] Nyxoid (UK) [QY]

Drugs for treatment of hyperkalemia and hyperphosphatemia

▪ LANTHANUM

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5491

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 1 g chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9405B NP	1	5	..	436.39	31.60	Fosrenol [TK]

lanthanum 500 mg chewable tablet, 2 x 45

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9403X NP	1	5	..	261.13	31.60	Fosrenol [TK]

lanthanum 750 mg chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9404Y NP	1	5	..	390.02	31.60	Fosrenol [TK]

▪ LANTHANUM

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14872

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 1 g chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13874F NP	2	5	..	*864.31	31.60	Fosrenol [TK]

lanthanum 500 mg chewable tablet, 2 x 45

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14060B NP	2	5	..	*513.81	31.60	Fosrenol [TK]

lanthanum 750 mg chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13986D NP	2	5	..	*771.57	31.60	Fosrenol [TK]

▪ PATIROMER

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14327

Chronic hyperkalaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor.

Treatment criteria:

- Patient must not be undergoing dialysis.

patiromer 8.4 g powder for oral liquid, 30 sachets

13609G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	376.38	31.60	Veltassa [CS]

patiromer 16.8 g powder for oral liquid, 30 sachets

13613L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	376.38	31.60	Veltassa [CS]

▪ PATIROMER

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

Chronic hyperkalaemia

Treatment Phase: Initial PBS-subsidised treatment (including grandfathered patients)

Population criteria:

- Patient must have stage 3 to stage 4 chronic kidney disease.

Clinical criteria:

- The condition must be inadequately controlled by a low potassium diet., **AND**
- Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; OR
- Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia.

Treatment criteria:

- Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease.

patiromer 8.4 g powder for oral liquid, 30 sachets

13610H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	376.38	31.60	Veltassa [CS]

patiromer 16.8 g powder for oral liquid, 30 sachets

13620W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	376.38	31.60	Veltassa [CS]

▪ SEVELAMER

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority required (STREAMLINED)

5491

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

2142R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	187.75	31.60	[a] Renagel [GZ]

sevelamer carbonate 800 mg tablet, 180

11856B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	187.75	31.60	[a] ARX-SEVELAMER [XT] [a] Sevelamer Lupin [GQ]	[a] Sevelamer Apotex [TX]

▪ SEVELAMER

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority required (STREAMLINED)

14984

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

13934J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*367.03	31.60	[a] Renagel [GZ]

sevelamer carbonate 800 mg tablet, 180

14027G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*367.03	31.60	[a] ARX-SEVELAMER [XT] [a] Sevelamer Lupin [GQ]	[a] Sevelamer Apotex [TX]

▪ SUCROFERRIC OXYHYDROXIDE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5491

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

10250L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	412.50	31.60	Velphoro [VL]

▪ SUCROFERRIC OXYHYDROXIDE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

14872

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13985C NP	2	5	..	*816.55	31.60	Velphoro [VL]

Detoxifying agents for antineoplastic treatment

▪ FOLINIC ACID

folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1704Q	1	1	..	60.55	31.60	Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1610R	1	2	..	55.29	31.60	Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

▪ FOLINIC ACID

Restricted benefit

Megaloblastic anaemias

Clinical criteria:

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

folinic acid 15 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2308L	1	..	..	95.18	31.60	Leucovorin Calcium (Hospira Pty Limited) [PF]

▪ MESNA

Restricted benefit

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

Clinical criteria:

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

mesna 1 g/10 mL injection, 15 x 10 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8079F	1	5	..	140.73	31.60	Uromitexan [BX]

mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8078E	1	5	..	69.09	31.60	Uromitexan [BX]

Drugs for treatment of hypercalcemia

▪ PHOSPHORUS

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5095

Familial hypophosphataemia

Authority required (STREAMLINED)

5123

Hypercalcaemia

phosphorus 500 mg effervescent tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2946C NP	1	5	..	81.83	31.60	PHOSPHATE PHEBRA [FG]

▪ PHOSPHORUS

Authority required (STREAMLINED)

14874
Hypophosphataemic rickets
Clinical criteria:
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

14962
Vitamin D-resistant rickets
Clinical criteria:
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

14921
Familial hypophosphataemia
Clinical criteria:
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

14922
Hypercalcaemia
Clinical criteria:
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

phosphorus 500 mg effervescent tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13850Y NP	2	5	..	*152.03	31.60	PHOSPHATE PHEBRA [FG]

Other therapeutic products

▪ POLYLACTIC ACID

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Severe facial lipoatrophy
Treatment Phase: Initial PBS-subsidised treatment
Clinical criteria:
- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

polylactic acid 150 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9475Q	2	4	..	*387.37	31.60	Sculptra [GA]

▪ POLYLACTIC ACID

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.
Note Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Severe facial lipoatrophy
Treatment Phase: Maintenance PBS-subsidised treatment
Clinical criteria:
- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

polylactic acid 150 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9476R	2	..	..	*387.37	31.60	Sculptra [GA]

DIAGNOSTIC AGENTS

URINE TESTS

GLUCOSE AND KETONE INDICATOR URINE

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

glucose and ketone indicator urine diagnostic strip, 50

3107M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*21.25	22.70	Keto-Diastix [DX]

NP

GLUCOSE INDICATOR URINE

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

glucose indicator urine diagnostic strip, 50

3104J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*20.83	22.28	Diastix [DX]

NP

GENERAL NUTRIENTS

OTHER NUTRIENTS

MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6181

Chylous ascites

Authority required (STREAMLINED)

6134

Chylothorax

Authority required (STREAMLINED)

6164

Fat malabsorption

Clinical criteria:

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)

6203

Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)

6155

Intractable childhood epilepsy

Clinical criteria:

- Patient must require a ketogenic diet.

Authority required (STREAMLINED)

6135

Cerebrospinal fluid glucose transporter defect

Clinical criteria:

- Patient must require a ketogenic diet.

Authority required (STREAMLINED)

6146

Long chain fatty acid oxidation disorders

medium chain triglycerides oral liquid, 250 mL bottle

9327X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*170.59	31.60	Liquigen [SB]

NP

medium chain triglycerides oral oil, 500 mL

3128P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*47.15	31.60	MCT Oil [SB]

NP

PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS

Note No increase in the maximum number of repeats may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

Population criteria:

- Patient must be aged from 1 to 10 years inclusive.

protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 12 x 500 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11939J NP	7	5	..	*1583.74	31.60	Nutrini Peptisorb Energy [NU]

Fat/carbohydrates/proteins/minerals/vitamins, combinations

▪ AMINO ACID SYNTHETIC FORMULA

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1521C NP	12	5	..	*439.23	31.60	Neocate Junior Vanilla [SB]

amino acid synthetic formula powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2250K NP	12	5	..	*439.23	31.60	EleCare [AB]

▪ AMINO ACID SYNTHETIC FORMULA

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula powder for oral liquid, 400 g

1180D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*295.63	31.60	Neocate Junior Vanilla [SB]

amino acid synthetic formula powder for oral liquid, 400 g

8574G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*295.63	31.60	EleCare [AB]

▪ AMINO ACID SYNTHETIC FORMULA

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

amino acid synthetic formula powder for oral liquid, 400 g

1192R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*295.63	31.60	Neocate Junior Vanilla [SB]

amino acid synthetic formula powder for oral liquid, 400 g

8575H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*295.63	31.60	EleCare [AB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

2246F

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*316.83	31.60	Neocate LCP [SB]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

9339M

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*236.35	31.60	EleCare LCP [AB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

2560R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	Neocate LCP [SB]

NP

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

9340N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*236.35	31.60	EleCare LCP [AB]

NP

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

1545H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12	5	..	*471.03	31.60	Neocate Gold [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

5466Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	Neocate Gold [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

5467R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	Neocate Gold [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Alfamino products that contain 2-fucoscyllactose and lacto-N-neoterose and Alfamino products that do not contain 2-fucoscyllactose and lacto-N-neoterose are equivalent for the purposes of substitution.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g

13615N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	[a] Alfamino [NT]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

2900P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	[a] Alfamino [NT]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Alfamino products that contain 2-fucosyllactose and lacto-N-neoterose and Alfamino products that do not contain 2-fucosyllactose and lacto-N-neoterose are equivalent for the purposes of substitution.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g

13627F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	[a] Alfamino [NT]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

2928D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*316.83	31.60	[a] Alfamino [NT]

▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6174

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)

6193

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)

6204

Cows' milk protein enteropathy and intolerance to soy protein

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6137

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6182

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6194

Biliary atresia

Authority required (STREAMLINED)

6157

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205

Chylous ascites

Authority required (STREAMLINED)

6195

Cystic fibrosis

Authority required (STREAMLINED)

6158

Enterokinase deficiency

Authority required (STREAMLINED)

6166

Proven fat malabsorption

Authority required (STREAMLINED)

6148

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

- Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138

Severe intestinal malabsorption including short bowel syndrome

protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g

8259Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*202.67	31.60	Aptamil Gold+ Pepti-Junior [NU]

▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6174

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)

6193

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)

6204

Cows' milk protein enteropathy and intolerance to soy protein

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6137

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6182

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6194

Biliary atresia

Authority required (STREAMLINED)

6157

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205

Chylous ascites

Authority required (STREAMLINED)

6195

Cystic fibrosis

Authority required (STREAMLINED)

6158

Enterokinase deficiency

Authority required (STREAMLINED)

6166

Proven fat malabsorption

Authority required (STREAMLINED)

6148

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

- Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138

Severe intestinal malabsorption including short bowel syndrome

Authority required (STREAMLINED)

6206

Chylothorax

protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g

2676W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*136.83	31.60	Alfaré [NT]

NP

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula powder for oral liquid, 400 g

10152H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*404.35	31.60	Monogen [SB]

NP

triglycerides medium chain formula powder for oral liquid, 400 g

10155L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*365.31	31.60	Lipistart [VF]

NP

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum number of repeats may be authorised.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula powder for oral liquid, 400 g

10154K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*265.23	31.60	Peptamen Junior [NT]

NP

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula oral liquid, 12 x 500 mL bottles

12948L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12	5	..	*1553.07	31.60	Nutrini Peptisorb [SB]

NP

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit
Hyperlipoproteinaemia type 1
Restricted benefit
Long chain fatty acid oxidation disorders
Restricted benefit
Chylous ascites
Restricted benefit
Chylothorax

triglycerides medium chain formula powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1938B NP	8	5	..	*365.31	31.60	Lipistart [VF]

triglycerides medium chain formula powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8478F NP	8	5	..	*404.35	31.60	Monogen [SB]

Carbohydrates

▪ MODIFIED LONG CHAIN AMYLOPECTIN

Restricted benefit
Glycogen storage disease

modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9386B NP	4	5	..	*652.31	31.60	Glycosade [VF]

Amino acids/carbohydrates/minerals/vitamins, combinations

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required
Cows' milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 months
Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months
Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months
Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

10522T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*344.35	31.60	Alfamino Junior [NT]

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

11161K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*344.35	31.60	Neocate Junior [SB]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

10527C

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*344.35	31.60	Alfamino Junior [NT]

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11183N NP	8	5	..	*344.35	31.60	Neocate Junior [SB]

Milk substitutes

▪ MILK POWDER SYNTHETIC LOW CALCIUM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Hypercalcaemia

Population criteria:

- Patient must be under the age of 4 years.

milk powder synthetic low calcium powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3092R NP	8	5	..	*364.59	31.60	Locasol [SB]

Other combinations of nutrients

▪ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11343B NP	12	5	..	*477.51	31.60	Neocate Syneo [SB]

▪ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

11331J

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*321.23	31.60	Neocate Syneo [SB]

▪ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Note A risk/benefit analysis prior to treatment, and continuous patient monitoring from a health care professional is required for the use of this product, for this indication.

amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11340W NP	8	5	..	*321.23	31.60	Neocate Syneo [SB]

▪ AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE

Note This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

Restricted benefit

Phenylketonuria

amino acid formula with carbohydrate without phenylalanine modified release tablet, 6 x 77

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12072J NP	4	5	..	*1323.11	31.60	PKU Easy Tablet [OH]

▪ AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine powder for oral liquid, 30 x 20 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10806R NP	4	5	..	*957.79	31.60	PKU Go [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE

Note This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with fat, carbohydrate without methionine modified release tablet, 6 x 77

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12006X NP	5	5	..	*2962.77	31.60	HCU Easy Tablet [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10683G NP	7	5	..	*1850.65	31.60	PKU Easy Microtabs [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE

Note This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate without phenylalanine and tyrosine modified release tablet, 6 x 77

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12015J NP	4	5	..	*2402.75	31.60	TYR Easy Tablet [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Note This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

Restricted benefit

Maple syrup urine disease

amino acid formula with fat, carbohydrate without valine, leucine and isoleucine modified release tablet, 6 x 77

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12014H NP	5	5	..	*2962.77	31.60	MSUD Easy Tablet [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3417W NP	4	5	..	*2181.79	31.60	HCU Anamix junior LQ [SB]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10632N NP	5	5	..	*1827.67	31.60	PKU Easy Shake & Go [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles

9330C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*2181.79	31.60	TYR Anamix junior LQ [SB]

NP

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS, WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements, without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g bottles

10934L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*2826.83	31.60	TYR Easy Shake & Go [OH]

NP

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 800 g

12650T

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*336.55	31.60	Essential Care Jr [QH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 800 g

12643K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*336.55	31.60	Essential Care Jr [QH]

NP

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets

10715Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*1832.11	31.60	GA1 Anamix Junior [NU]

NP

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2650L NP	8	5	..	*666.99	31.60	GA1 Anamix infant [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10466W NP	9	5	..	*2670.24	31.60	XLYS, LOW TRY Maxamum [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

Restricted benefit

Pyridoxine dependent epilepsy

Clinical criteria:

- Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9438R NP	4	5	..	*1832.11	31.60	GA gel [VF]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 125 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1548L NP	3	5	..	*2560.35	31.60	HCU Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8744F NP	4	5	..	*2560.39	31.60	HCU express 15 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2640Y NP	4	5	..	*3359.63	31.60	HCU cooler 20 [VF]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 29 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12273Y NP	4	5	..	*3359.63	31.60	HCU Lophlex [SB]

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10693T NP	4	5	..	*1743.79	31.60	HCU Anamix Junior [NU]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

Population criteria:

- Patient must be an infant or a very young child.

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8417B NP	8	5	..	*634.11	31.60	HCU Anamix infant [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit

Methylmalonic acidaemia

Restricted benefit
Propionic acidaemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8058D NP	8	5	..	*634.11	31.60	MMA/PA Anamix infant [SB]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3443F NP	4	5	..	*2560.39	31.60	MMA/PA express 15 [VF]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit
Methylmalonic acidaemia
Restricted benefit
Propionic acidaemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 18 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10730R NP	8	5	..	*1743.71	31.60	MMA/PA Anamix Junior [NU]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Restricted benefit
Phenylketonuria

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5483N NP	4	5	..	*868.55	31.60	PKU squeezie [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9021T NP	4	5	..	*1672.95	31.60	PKU Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9396M NP	4	5	..	*1041.75	31.60	PKU Anamix Junior LQ [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8846N NP	4	5	..	*1270.11	31.60	PKU Cooler 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10411Y NP	4	5	..	*1692.27	31.60	PKU Air 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2474F NP	4	5	..	*1692.27	31.60	PKU Cooler 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8746H NP	5	5	..	*852.52	31.60	Easiphen [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9397N NP	2	5	..	*680.69	31.60	PKU Lophlex LQ 10 [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2382J NP	4	5	..	*849.63	31.60	PKU Cooler 10 [VF]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2739E NP	8	5	..	*1109.55	31.60	XP Maxamum [SB]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8591E NP	4	5	..	*1270.79	31.60	PKU express 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 34 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1909L NP	4	5	..	*1692.27	31.60	PKU express 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g tubs

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2806Q NP	3	5	..	*1520.64	31.60	PKU Lophlex Sensation 20 [SB]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 28 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12136R NP	4	5	..	*1672.95	31.60	PKU Lophlex [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Phenylketonuria

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10258X NP	4	5	..	*869.51	31.60	PKU Anamix Junior [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8445L NP	8	5	..	*634.11	31.60	TYR Anamix infant [SB]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 125 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1547K NP	3	5	..	*2023.56	31.60	TYR Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2701E NP	4	5	..	*3359.63	31.60	TYR cooler 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 28 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12274B NP	4	5	..	*3359.63	31.60	TYR Lophlex [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10260B NP	4	5	..	*1743.79	31.60	TYR Anamix Junior [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2380G NP	8	5	..	*634.11	31.60	MSUD Anamix infant [SB]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 125 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1546J NP	3	5	..	*2560.35	31.60	MSUD Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2375B NP	4	5	..	*2560.39	31.60	MSUD cooler 15 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8057C NP	8	5	..	*2240.67	31.60	MSUD Maxamum [SB]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8632H NP	4	5	..	*2560.39	31.60	MSUD express 15 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2654Q NP	4	5	..	*3359.63	31.60	MSUD cooler 20 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 28 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12285N NP	4	5	..	*3359.63	31.60	MSUD Lophlex [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10259Y NP	4	5	..	*1743.79	31.60	MSUD Anamix Junior [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9499Y NP	4	5	..	*2181.79	31.60	MSUD Anamix Junior LQ [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14118C NP	8	5	..	*1743.79	31.60	MSUD explore5 [VF]

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID**

Restricted benefit

Phenylketonuria

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets

11185Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*957.71	31.60	PKU Anamix First Spoon [SB]

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets

11859E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*957.71	31.60	PKU Explore 5 [VF]

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 25 g sachets

11836Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*957.75	31.60	PKU Explore 10 [VF]

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals, without methionine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

14114W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*1743.79	31.60	HCU explore5 [VF]

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

14126L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*1743.79	31.60	TYR explore5 [VF]

- **AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**

Restricted benefit

Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g

8479G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*580.19	31.60	PKU Anamix infant [SB]

- **AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**

Note The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

Restricted benefit

Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g

11653H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*616.59	31.60	PKU Start [VF]

- **AMINO ACID FORMULA WITHOUT PHENYLALANINE**

Restricted benefit

Phenylketonuria

amino acid formula without phenylalanine 1 g tablet, 75

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8678R NP	24	5	..	*1170.75	31.60	Phlexy-10 [SB]

▪ AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 6 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10161T NP	12	5	..	*2967.03	31.60	MSUD amino5 [VF]

▪ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

Restricted benefit

Peroxisomal biogenesis disorders

arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10036F NP	4	5	..	*336.71	31.60	keyomega [VF]

▪ ARGININE WITH CARBOHYDRATE

Note Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders

arginine with carbohydrate containing 2 g arginine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5482M NP	4	5	..	*668.31	31.60	Arginine 2000 [VF]

arginine with carbohydrate containing 500 mg arginine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9437Q NP	4	5	..	*448.35	31.60	Arginine 500 [VF]

arginine with carbohydrate containing 5 g arginine powder for oral liquid, 30 x 7.6 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10093F NP	4	5	..	*881.59	31.60	Arginine 5000 [VF]

▪ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8369L NP	8	5	..	*259.07	31.60	Energivit [SB]

▪ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10039J NP	4	5	..	*432.79	31.60	basecal 200 [VF]

▪ CITRULLINE

Note Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

Restricted benefit

Urea cycle disorders

Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline 1 g tablet, 300

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10736C NP	‡1	5	..	1144.94	31.60	Citrulline Easy [OH]

▪ CITRULLINE WITH CARBOHYDRATE

Note Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders

Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5481L NP	4	5	..	*448.35	31.60	Citrulline 1000 [VF]

▪ ESSENTIAL AMINO ACIDS FORMULA

Restricted benefit

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula powder for oral liquid, 2 x 200 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9329B NP	6	5	..	*1033.29	31.60	Essential Amino Acid Mix [SB]

▪ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

Restricted benefit

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2027Q NP	5	5	..	*523.27	31.60	Dialamine [SB]

▪ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

Restricted benefit

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula with vitamins and minerals powder for oral liquid, 30 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13759E NP	6	5	..	*1181.97	31.60	EAA Supplement [VF]

▪ GLYCINE WITH CARBOHYDRATE

Restricted benefit

Isovaleric acidaemia

glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10195N NP	4	5	..	*497.23	31.60	Glycine500 [VF]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE

Restricted benefit

Tyrosinaemia

glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 35 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11832R NP	4	5	..	*4098.63	31.60	TYR Sphere20 [VF]

glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 31 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12175T NP	4	5	..	*3359.63	31.60	Tylactin Build 20 [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Restricted benefit

Tyrosinaemia

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11290F NP	8	5	..	*2780.03	31.60	Tylactin Complete [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10528D NP	4	5	..	*2967.03	31.60	Tylactin RTD [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Restricted benefit

Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 40 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13714T NP	4	5	..	*1580.39	31.60	Camino Pro Bettermilk [QH]

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11084J NP	5	5	..	*1317.87	31.60	PKU Restore [QH]

glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2644E NP	14	5	..	*1294.43	31.60	Camino Pro Complete [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Note This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

Restricted benefit

Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10332T NP	4	5	..	*1580.35	31.60	PKU Glytactin RTD 15 [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11640P NP	4	5	..	*1580.35	31.60	PKU Glytactin RTD 15 Lite [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Note This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.

Restricted benefit

Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11287C NP	2	5	..	*1075.35	31.60	PKU Build 10 [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11279P NP	4	5	..	*2085.39	31.60	PKU Build 20 [QH]

▪ GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

Restricted benefit

Phenylketonuria

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 15 x 237 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13257R NP	8	5	..	*1984.43	31.60	PKU Sphere Liquid [VF]

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11071Q NP	4	5	..	*1984.39	31.60	PKU Sphere20 [VF]

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11245W NP	4	5	..	*1504.63	31.60	PKU Sphere15 [VF]

▪ GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

Note This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

Restricted benefit

Phenylketonuria

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 18 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11844J NP	10	5	..	*1504.57	31.60	PKU GMPro LQ [SB]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Requests seeking an increased maximum quantity (packs) up to 4 times that stated, may be authorised.

Restricted benefit

Ketogenic diet

Treatment criteria:

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12635B NP	4	5	..	*794.79	31.60	K.Yo [VF]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10185C NP	5	5	..	*940.02	31.60	KetoCal 4:1 LQ [SB]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Treatment criteria:

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12456N NP	6	5	..	*1360.77	31.60	KetoVie 4:1 [QH]

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12464B NP	6	5	..	*929.73	31.60	KetoVie 3:1 [QH]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2652N NP	24	5	..	*985.23	31.60	KetoCal 3:1 [SB]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydate plus protein) powder for oral liquid, 300 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9446E NP	24	5	..	*985.23	31.60	KetoCal 4:1 [SB]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency, **AND**
- Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula, **AND**
- Patient must have unsuccessfully trialled at least one of the PBS-listed products with the indication of: 'Ketogenic diet'.

This product must only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12789D NP	6	5	..	*1540.41	31.60	KetoVie Peptide 4:1 [QH]

▪ ISOLEUCINE WITH CARBOHYDRATE

Restricted benefit

Maple syrup urine disease

isoleucine with carbohydrate containing 1 g isoleucine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9436P NP	4	5	..	*492.35	31.60	Isoleucine 1000 [VF]

isoleucine with carbohydrate containing 50 mg isoleucine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9134R NP	4	5	..	*448.35	31.60	Isoleucine 50 [VF]

▪ MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8630F NP	24	5	..	*909.63	31.60	Carbohydrate Free Mixture [SB]

▪ PHENYLALANINE WITH CARBOHYDRATE

Restricted benefit

Tyrosinaemia

phenylalanine with carbohydrate containing 50 mg phenylalanine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9384X NP	4	5	..	*448.35	31.60	Phenylalanine 50 [VF]

▪ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit

Phenylketonuria

protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10658Y NP	5	5	..	*1826.67	31.60	PKU Easy [OH]

▪ PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A

Authority required (STREAMLINED)

11070

Chronic renal failure

Population criteria:

- Patient must be a child aged 3 years or older.

Clinical criteria:

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A oral liquid, 24 x 125 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12191P NP	8	5	..	*1329.55	31.60	Renastep [VF]

▪ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8577K NP	120	5	..	*552.27	31.60	RCF [AB]

▪ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9309Y NP	4	5	..	*259.47	31.60	ProZero [VF]

triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9308X NP	6	5	..	*291.57	31.60	ProZero [VF]

triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10189G NP	2	5	..	*159.79	31.60	Sno-Pro [SB]

▪ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3136C NP	8	5	..	*239.71	31.60	Duocal [SB]

▪ TYROSINE WITH CARBOHYDRATE

Note This formulation is suitable for patients aged 3 and older.

Restricted benefit

Phenylketonuria

tyrosine with carbohydrate containing 1 g tyrosine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9165J NP	4	5	..	*448.35	31.60	Tyrosine 1000 [VF]

▪ VALINE WITH CARBOHYDRATE

Restricted benefit

Maple syrup urine disease

valine with carbohydrate containing 1 g valine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9434M NP	4	5	..	*492.35	31.60	Valine 1000 [VF]

valine with carbohydrate containing 50 mg valine powder for oral liquid, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9135T NP	4	5	..	*448.35	31.60	Valine 50 [VF]

▪ VITAMINS, MINERALS AND TRACE ELEMENTS

Note Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.

Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

- Patient must be aged 3 years or older.

vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11200L NP	1	5	..	282.27	31.60	Phlexy-Vits [SB]

▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

- Patient must be aged 3 years or older.

vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10149E NP	1	5	..	254.88	31.60	FruitiVits [VF]

▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

- Patient must be an infant or a child.

vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9328Y NP	6	5	..	*336.99	31.60	Paediatric Seravit [SB]

▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

Authority required (STREAMLINED)

6190

Chronic renal failure

Population criteria:

- Patient must be an infant or a young child.

Clinical criteria:

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 6 x 400 g cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2870C NP	4	5	..	*1364.55	31.60	Renastart [VF]

▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

Authority required (STREAMLINED)

6190

Chronic renal failure

Population criteria:

- Patient must be an infant or a young child.

Clinical criteria:

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g

8587Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
16	5	..	*874.43	31.60	Kindergen [SB]

Palliative Care

ALIMENTARY TRACT AND METABOLISM....1622

STOMATOLOGICAL PREPARATIONS 1622
STOMATOLOGICAL PREPARATIONS.... 1622
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS.... 1622
BELLADONNA AND DERIVATIVES, PLAIN 1622
PROPULSIVES.... 1622
DRUGS FOR CONSTIPATION 1622
DRUGS FOR CONSTIPATION.... 1622

MUSCULO-SKELETAL SYSTEM....1623

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS.... 1623
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS.... 1623

NERVOUS SYSTEM....1624

ANALGESICS.... 1624
OPIOIDS 1624
OTHER ANALGESICS AND ANTIPYRETICS.... 1641
ANTIEPILEPTICS.... 1642
ANTIEPILEPTICS 1642
PSYCHOLEPTICS.... 1642
ANTIPSYCHOTICS.... 1642
ANXIOLYTICS 1642
HYPNOTICS AND SEDATIVES 1643

Palliative

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Other agents for local oral treatment

BENZYDAMINE

Authority required (STREAMLINED)

6197

Painful mouth

Clinical criteria:

- Patient must be receiving palliative care.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5385K NP	‡1	3	..	22.17	23.62	Difflam [IL]

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

Authority required (STREAMLINED)

6207

For use in patients receiving palliative care

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5317W NP	6	3	..	*55.83	31.60	[a] Buscopan [VZ]	[a] HYOSCINE BUTYLBROMIDE-AFT [AE]
						[a] HYOSCINE BUTYLBROMIDE MEDSURGE [DZ]	[a] HYOSCINE BUTYLBROMIDE SXP [XN]

PROPULSIVES

Propulsives

METOCLOPRAMIDE

Authority required (STREAMLINED)

6084

Nausea or gastric stasis

Clinical criteria:

- Patient must be receiving palliative care.

metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10762K NP	4	2	..	*43.99	31.60	METOCLOPRAMIDE INJECTION BP [WZ]

METOCLOPRAMIDE

Restricted benefit

For use in patients receiving palliative care

metoclopramide hydrochloride 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12507G NP	4	5	..	*$24.23	25.68	[a] APO-Metoclopramide [TX]	[a] EMEXLON [RW]
						[a] Pramin [AF]	
			[B]14.20	*38.43	25.68	[a] Maxolon [IL]	

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Osmotically acting laxatives

MACROGOL-3350

Authority required (STREAMLINED)

6170

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

macrogol-3350 1 g/g powder for oral liquid, 510 g

5426N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*32.41	31.60	OsmoLax [KY]

NP

▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

Authority required (STREAMLINED)

6171

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

5389P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*28.61	30.06	[a] APOHEALTH Macrogol with Electrolytes [GX] [a] Chemists' Own Macrogol with Electrolytes [RW] [a] Molaxole [GO]	[a] APO-MACROGOL plus ELECTROLYTES [TX] [a] Macrovic [RF]
		[B]4.24	*32.85	30.06	[a] Movicol [NE]	

NP

Enemas

▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL

5331N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*37.21	31.60	Micolette [AE]

NP

Peripheral opioid receptor antagonists

▪ METHYLNALTREXONE

Authority required (STREAMLINED)

6180

Opioid-induced constipation

Clinical criteria:

- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial

5423K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
7	..	..	*244.99	31.60	Relistor [LM]

NP

methylnaltrexone bromide 12 mg/0.6 mL injection, 7 x 0.6 mL vials

5424L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	244.99	31.60	Relistor [LM]

NP

▪ MUSCULO-SKELETAL SYSTEM

▪ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Acetic acid derivatives and related substances

▪ INDOMETACIN

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

indometacin 25 mg capsule, 50

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*20.13	21.58	[a] Arthrexin [AF]

5377B NP		[B]4.04	*24.17	21.58	[a] Indocid [AS]	

Propionic acid derivatives

▪ IBUPROFEN

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5368M NP	3	3	..	*21.54	22.99	[a] APO-Ibuprofen 400 [TX]	[a] MEDICHOICE Ibuprofen 400 mg [NB]
			[B]7.53	*29.07	22.99	[a] Brufen [GO]	

▪ NAPROXEN

Restricted benefit

Severe pain

Treatment criteria:

- Patient must be undergoing palliative care.

Clinical criteria:

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

naproxen 125 mg/5 mL oral liquid, 474 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5397C NP	‡1	3	..	124.15	31.60	Phebra Naproxen Suspension [FF]

▪ NAPROXEN

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

naproxen 1 g modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5348L NP	1	3	..	19.28	20.73	[a] Proxen SR 1000 [IY]
			[B]2.35	21.63	20.73	[a] Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5345H NP	2	3	..	*21.89	23.34	Naprosyn [IX]

naproxen 750 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5347K NP	1	3	..	17.93	19.38	[a] Proxen SR 750 [IY]
			[B]2.35	20.28	19.38	[a] Naprosyn SR750 [IX]

▪ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

naproxen sodium 550 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5353R NP	1	3	..	18.42	19.87	[a] Crysanal [IY]
			[B]2.85	21.27	19.87	[a] Anaprox 550 [IX]

▪ NERVOUS SYSTEM

▪ ANALGESICS

OPIOIDS

Natural opium alkaloids

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

11697
Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14084G NP	1	1	..	435.42	31.60	pms-HYDROmorphone [DZ]

hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12531M NP	2	1	..	*35.02	31.60	[a] Dilaudid-HP [MF]	[a] Hydromorphone-hameln-HP [HW]
						[a] HYDROMORPHONE JUNO-HP [JU]	[a] MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ]

hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12493M NP	2	1	..	*30.96	31.60	[a] Dilaudid [MF]	[a] Hydromorphone-hameln [HW]
						[a] HYDROMORPHONE JUNO [JU]	[a] MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ]

hydromorphone hydrochloride 2 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12497R NP	2	1	..	*32.02	31.60	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12484C NP	2	1	..	*36.56	31.60	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12515Q NP	2	1	..	*53.38	31.60	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Note Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

Authority required (STREAMLINED)

11697
Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

12565H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	351.38	31.60	[a] Hikma [LM]

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

13806P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	435.42	31.60	[a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

Authority required

Severe disabling pain

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 10 mg tablet, 20

5393W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	23.35	24.80	Sevredol [MF]

morphine sulfate pentahydrate 20 mg tablet, 20

5394X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	24.10	25.55	Sevredol [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
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[Your capital city]

Authority required (STREAMLINED)

11697

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate 10 mg/5 mL oral solution, 100 mL

13742G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	1	..	*688.34	31.60	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

morphine sulfate 10 mg/5 mL oral solution, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13741F NP	7	1	..	*724.68	31.60	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

morphine sulfate 2 mg/mL oral solution, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13743H NP	10	1	..	*493.94	31.60	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

morphine sulfate 2 mg/mL oral solution, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13748N NP	4	1	..	*447.52	31.60	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12548K NP	2	1	..	*34.28	31.60	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12503C NP	2	1	..	*38.48	31.60	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12494N NP	2	1	..	*33.40	31.60	Morphine Juno [JU]

morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12470H NP	2	1	..	*43.10	31.60	Morphine Juno [JU]

morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12537W NP	2	1	..	*59.26	31.60	Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Morphini HCl Streuli or the brand RA-Morph (NZ) can be substituted for pharmaceutical benefits that have the brand Ordine 10 in case of a shortage.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Authority required (STREAMLINED)

11697

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14081D NP	20	1	..	*1119.04	31.60	[a] Morphini HCl Streuli [DZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12472K NP	2	1	..	*52.80	31.60	[a] Ordine 10 [XT]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14187Q NP	2	1	..	*296.08	31.60	[a] RA-Morph (NZ) [WZ]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Authority required (STREAMLINED)

11697

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12499W NP	2	1	..	*28.76	30.21	[a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12502B NP	2	1	..	*28.34	29.79	[a] Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand RA-Morph (NZ) can be substituted for Ordine 5 in case of shortage.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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[Your capital city]

Authority required (STREAMLINED)

11697

Severe pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

12549L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*47.70	31.60	[a] Ordine 5 [XT]

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

14186P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*194.48	31.60	[a] RA-Morph (NZ) [WZ]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

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Authority required

Severe disabling pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

morphine sulfate pentahydrate 10 mg modified release capsule, 28

12501Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*37.80	31.60	Kapanol [YN]

morphine sulfate pentahydrate 100 mg modified release capsule, 28

12529K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*102.68	31.60	Kapanol [YN]

morphine sulfate pentahydrate 120 mg modified release capsule, 14

12512M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*80.24	31.60	MS Mono [MF]

morphine sulfate pentahydrate 20 mg modified release capsule, 28

12539Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*39.60	31.60	Kapanol [YN]

morphine sulfate pentahydrate 30 mg modified release capsule, 14

12490J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*38.56	31.60	MS Mono [MF]

morphine sulfate pentahydrate 50 mg modified release capsule, 28

12489H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*63.52	31.60	Kapanol [YN]

morphine sulfate pentahydrate 60 mg modified release capsule, 14

12487F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*53.78	31.60	MS Mono [MF]

morphine sulfate pentahydrate 90 mg modified release capsule, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12514P NP	2	..	..	*61.08	31.60	MS Mono [MF]

morphine sulfate pentahydrate 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12547J NP	2	..	..	*33.12	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

morphine sulfate pentahydrate 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12483B NP	2	..	..	*105.48	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

morphine sulfate pentahydrate 15 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12476P NP	2	..	..	*45.10	31.60	MS Contin [MF]

morphine sulfate pentahydrate 200 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5391R NP	2	..	..	*229.04	31.60	MS Contin [MF]

morphine sulfate pentahydrate 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12500X NP	2	..	..	*53.82	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

morphine sulfate pentahydrate 5 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12492L NP	2	..	..	*32.38	31.60	MS Contin [MF]

morphine sulfate pentahydrate 60 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12544F NP	2	..	..	*80.26	31.60	[a] MORPHINE MR APOTEX [TX] [a] MS Contin [MF]	[a] Morphine MR Mylan [AF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Morphine sulfate pentahydrate 10 and 20 mg modified release capsules must not be co-prescribed with immediate release oral morphine, when it has been prescribed for the reduction of chronic breathlessness.

Note Treatment should be initiated by a specialist knowledgeable in the use of potent opioids for the management of chronic breathlessness.

Note Applications for an increased maximum quantity to provide for 1 month's supply of this drug will be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic Breathlessness

Clinical criteria:

- Patient must be receiving palliative care.

morphine sulfate pentahydrate 10 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11760Y NP	1	..	..	28.31	29.76	Kapanol [YN]

morphine sulfate pentahydrate 20 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11761B NP	1	..	..	29.21	30.66	Kapanol [YN]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Authority required

Severe disabling pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12518W NP	2	..	..	*40.84	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 15 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12545G NP	2	..	..	*57.32	31.60	OxyContin [MF]

oxycodone hydrochloride 20 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12510K NP	2	..	..	*57.80	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12538X NP	2	..	..	*84.48	31.60	OxyContin [MF]

oxycodone hydrochloride 40 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12525F NP	2	..	..	*77.76	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 80 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12527H NP	2	..	..	*115.38	31.60	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

▪ OXYCODONE + NALOXONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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Authority required

Severe disabling pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12523D NP	2	..	..	*56.30	31.60	Targin 10/5mg [MF]

oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12486E NP	2	..	..	*85.28	31.60	Targin 20/10mg [MF]

oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12475N NP	2	..	..	*119.30	31.60	Targin 40/20mg [MF]

oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12522C NP	2	..	..	*54.04	31.60	Targin 5/2.5mg [MF]

oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12511L NP	2	..	..	*151.64	31.60	Targin 60/30 [MF]

oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12498T NP	2	..	..	*158.96	31.60	Targin 80/40 [MF]

oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12471J NP	2	..	..	*38.56	31.60	Targin 2.5/1.25 mg [MF]

oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12540B NP	2	..	..	*65.00	31.60	Targin 15/7.5mg [MF]

oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12532N NP	2	..	..	*97.58	31.60	Targin 30/15 mg [MF]

Phenylpiperidine derivatives

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 200 microgram lozenge, 9

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5401G NP	1	..	..	90.40	31.60	Actiq [TB]

fentanyl 400 microgram lozenge, 9

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5402H NP	1	..	..	90.40	31.60	Actiq [TB]

fentanyl 400 microgram sublingual tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10603C NP	1	..	..	81.71	31.60	Abstral [FK]

fentanyl 300 microgram sublingual tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10606F NP	1	..	..	81.71	31.60	Abstral [FK]

fentanyl 600 microgram sublingual tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10604D NP	1	..	..	81.71	31.60	Abstral [FK]

fentanyl 100 microgram sublingual tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10601Y NP	2	..	..	*145.88	31.60	Abstral [FK]

fentanyl 200 microgram sublingual tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10600X NP	2	..	..	*145.88	31.60	Abstral [FK]

fentanyl 800 microgram sublingual tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10612M NP	1	..	..	81.71	31.60	Abstral [FK]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 100 microgram orally disintegrating tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10729Q NP	2	..	..	*77.34	31.60	Fentora [TB]

fentanyl 200 microgram orally disintegrating tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10697B NP	2	..	..	*77.34	31.60	Fentora [TB]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.
Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.
Note Telephone approvals are limited to 1 months' therapy.

Authority required
Breakthrough pain
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 200 microgram lozenge, 30

5407N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*514.78	31.60	Actiq [TB]

fentanyl 400 microgram lozenge, 30

5408P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*514.78	31.60	Actiq [TB]

fentanyl 600 microgram lozenge, 30

5409Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*377.58	31.60	Actiq [TB]

fentanyl 800 microgram lozenge, 30

5410R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*377.58	31.60	Actiq [TB]

fentanyl 800 microgram sublingual tablet, 30

10611L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

fentanyl 100 microgram sublingual tablet, 30

10602B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

fentanyl 200 microgram sublingual tablet, 30

10607G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

fentanyl 400 microgram sublingual tablet, 30

10608H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

fentanyl 300 microgram sublingual tablet, 30

10610K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

fentanyl 600 microgram sublingual tablet, 30

10613N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.
Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.
Note Telephone approvals are limited to 1 months' therapy.

Authority required

Breakthrough pain

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 200 microgram orally disintegrating tablet, 28

10698C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*443.74	31.60	Fentora [TB]

fentanyl 400 microgram orally disintegrating tablet, 28

10737D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*285.36	31.60	Fentora [TB]

fentanyl 600 microgram orally disintegrating tablet, 28

10713W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*285.36	31.60	Fentora [TB]

fentanyl 800 microgram orally disintegrating tablet, 28

10738E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*285.36	31.60	Fentora [TB]

fentanyl 100 microgram orally disintegrating tablet, 28

10684H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*443.74	31.60	Fentora [TB]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 75 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12474M NP	2	..	..	*51.96	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 75 [JC]

fentanyl 75 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12517T NP	2	..	..	*59.78	31.60	[a] Fenpatch 75 [RW]

fentanyl 75 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12526G NP	2	..	..	*51.96	31.60	[a] Denpax [AF]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 50 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12477Q NP	2	..	..	*43.02	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 50 [JC]

fentanyl 50 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12513N NP	2	..	..	*48.70	31.60	[a] Fenpatch 50 [RW]

fentanyl 50 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12546H NP	2	..	..	*43.02	31.60	[a] Denpax [AF]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 100 microgram/hour patch, 5

12480W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*69.20	31.60	[a] Fenpatch 100 [RW]

fentanyl 100 microgram/hour patch, 5

12509J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*59.94	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 100 [JC]

fentanyl 100 microgram/hour patch, 5

12533P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*59.94	31.60	[a] Denpax [AF]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 12 microgram/hour patch, 5

12491K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.18	30.63	[a] Denpax [AF]

fentanyl 12 microgram/hour patch, 5

12530L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*31.62	31.60	[a] Fenpatch 12 [RW]

fentanyl 12 microgram/hour patch, 5

12541C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*29.18	30.63	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 12 [JC]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

fentanyl 25 microgram/hour patch, 5

12504D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*32.00	31.60	[a] APO-Fentanyl [TX] [a] Fentanyl Sandoz [SZ]	[a] Durogesic 25 [JC]

fentanyl 25 microgram/hour patch, 5

12516R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*32.00	31.60	[a] Denpax [AF]

fentanyl 25 microgram/hour patch, 5

12521B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*35.10	31.60	[a] Fenpatch 25 [RW]

Diphenylpropylamine derivatives

▪ METHADONE

Caution The risk of drug dependence is high.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 month's therapy.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Chronic severe disabling pain
Treatment Phase: Initial treatment, for up to 3 months
Clinical criteria:
- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5399E NP	1	2	..	27.33	28.78	Aspen Methadone Syrup [AS]

▪ METHADONE

Caution The risk of drug dependence is high.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 month's therapy.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Chronic severe disabling pain
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5400F NP	1	..	..	27.33	28.78	Aspen Methadone Syrup [AS]

▪ METHADONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note This treatment is not recommended for use in ambulant patients.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required
Severe disabling pain
Clinical criteria:
- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:
- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

methadone hydrochloride 10 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12520Y NP	6	..	..	*50.64	31.60	Physeptone [AS]

▪ METHADONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note This treatment is not recommended for use in ambulant patients.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Note Pharmaceutical benefits that have the form methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules and pharmaceutical benefits that have the form methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials are equivalent for the purposes of substitution.

Authority required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14193B NP	24	..	..	*906.84	31.60	Physeptone [AS]

Oripavine derivatives

▪ BUPRENORPHINE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

buprenorphine 10 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10948F NP	2	..	..	*45.98	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 20 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10970J NP	2	..	..	*60.70	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 5 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10957Q NP	2	..	..	*33.92	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 15 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10953L NP	2	..	..	*53.34	31.60	[a] B-Patch [IU] [a] Buprenorphine Sandoz [SZ]	[a] Bupredermal [TX] [a] Norspan [MF]

buprenorphine 25 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10964C NP	2	..	..	*67.68	31.60	[a] Bupredermal [TX] [a] Norspan [MF]	[a] Buprenorphine Sandoz [SZ]

buprenorphine 30 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10949G NP	2	..	..	*74.64	31.60	[a] Bupredermal [TX] [a] Norspan [MF]	[a] Buprenorphine Sandoz [SZ]

buprenorphine 40 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10959T NP	2	..	..	*88.62	31.60	[a] Bupredermal [TX] [a] Norspan [MF]	[a] Buprenorphine Sandoz [SZ]

OTHER ANALGESICS AND ANTIPYRETICS

Anilides

▪ PARACETAMOL

Restricted benefit

Analgesia or fever

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

paracetamol 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12210P NP	10	3	..	*98.47	31.60	Panadol [GJ]

▪ PARACETAMOL

Note Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

Restricted benefit

Analgesia or fever

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

paracetamol 665 mg modified release tablet, 96

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5343F NP	2	3	..	*20.99	22.44	[a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX] [a] Parapane OSTEO [AF]	[a] Osteomol 665 Paracetamol [CR]

paracetamol 665 mg modified release tablet, 192

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10796F NP	1	3	..	20.99	22.44	[a] Osteomol 665 Paracetamol [CR]	[a] Parapane OSTEO [AF]

Palliative

ANTIEPILEPTICS

ANTIEPILEPTICS

Benzodiazepine derivatives

CLONAZEPAM

Restricted benefit

For use in patients receiving palliative care

clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12534Q NP	1	1	..	24.03	25.48	Rivotril [PB]

CLONAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients receiving palliative care

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5339B NP	2	3	..	*20.99	22.44	Rivotril [PB]

clonazepam 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5338Y NP	1	3	..	22.95	24.40	Paxam 2 [AF]

CLONAZEPAM

Note Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients receiving palliative care

clonazepam 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5337X NP	1	3	..	20.23	21.68	[a] Paxam 0.5 [AF]

clonazepam 500 microgram tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11520H NP	2	3	[B]1.84	*22.09	21.70	[a] Rivotril [PB]

PSYCHOLEPTICS

ANTIPSYCHOTICS

Butyrophenone derivatives

HALOPERIDOL

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

For use in patients receiving palliative care

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12519X NP	1	2	..	24.66	26.11	Serenace [AS]

ANXIOLYTICS

Benzodiazepine derivatives

DIAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Anxiety

Clinical criteria:

- Patient must be receiving palliative care.

diazepam 2 mg tablet, 50

5355W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	16.37	17.82	[a] APO-Diazepam [TX] [a] Valpam 2 [RW]	[a] APX-Diazepam [TY]
		[B]2.78	19.15	17.82	[a] Antenex 2 [AF]	

diazepam 5 mg tablet, 50

5356X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	16.37	17.82	[a] Antenex 5 [AF] [a] APX-Diazepam [TY] [a] Valpam 5 [RW]	[a] APO-Diazepam [TX] [a] NOUMED DIAZEPAM [VO]
		[B]3.08	19.45	17.82	[a] Valium [IX]	

▪ OXAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Anxiety

Clinical criteria:

- Patient must be receiving palliative care.

oxazepam 30 mg tablet, 25

5372R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*18.89	20.34	[a] Alepam 30 [AF]	[a] APO-Oxazepam [TX]
		[B]1.68	*20.57	20.34	[a] Murelax [RW]	
		[B]7.84	*26.73	20.34	[a] Serepax [AS]	

oxazepam 15 mg tablet, 25

5371Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*18.89	20.34	[a] Alepam 15 [AF]	[a] Serepax [AS]

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

▪ NITRAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving palliative care.

nitrazepam 5 mg tablet, 25

5359C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*18.89	20.34	[a] Alodorm [AF]	[a] Mogadon [IL]

▪ TEMAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving palliative care.

temazepam 10 mg tablet, 25

5375X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	3	..	*18.89	20.34	[a] APO-Temazepam [TX] [a] Temtabs [LN]	[a] Temaze [AF]
		[B]10.14	*29.03	20.34	[a] Normison [AS]	

Repatriation Pharmaceutical Benefits Scheme

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card
This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

White card
A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

Orange card
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.

For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au

RPBS Explanatory Notes
Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient's full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
  - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the *National Health Act 1953*; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department's national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine

- dexamethasone
- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide

- For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.

- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

Contact the Department of Veterans' Affairs

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterens' Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580
Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

DRESSINGS

Pink Epithelialising Wound

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	• Film; • Film Island	• Gauze—Paraffin; • Non-adherent
(B) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate)	• Hydrocolloid (Superficial Wound—Light Exudate)

Red Granulating Wound

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	• Alginate (Superficial Wound); • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)	• Alginate (Cavity Wound); • Foam—Moderate Exudate (see “cavity conforming” product); • Hydroactive (Cavity Wound); • Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

Yellow Sloughy Wound

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Cadexomer Iodine; • Foam—Light Exudate; • Foam with Charcoal; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate Exudate)	• Cadexomer Iodine; • Hydrocolloid (Cavity Wound)
(B) Moisture Donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	• Alginate (Superficial Wound); • Cadexomer Iodine; • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate/High Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)	• Alginate (Cavity Wound); • Cadexomer Iodine; • Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

Black Necrotic Wound
Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous; • Hydrogel—Sheet

Infected Wounds
Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

Malodorous Wounds
Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.
Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

Minor Skin Trauma
Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

Ordering Products

Ordering Coloplast Products
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Ordering Hartmann Products
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

Ordering Molnlycke Healthcare Products
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

Ordering Smith & Nephew Products
Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

ALIMENTARY TRACT AND METABOLISM 1653
STOMATOLOGICAL PREPARATIONS 1653
STOMATOLOGICAL PREPARATIONS 1653
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS 1653
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS 1653
BELLADONNA AND DERIVATIVES, PLAIN 1653
DRUGS FOR CONSTIPATION 1653
DRUGS FOR CONSTIPATION 1653
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS 1654
ANTIPROPULSIVES 1654
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS 1655
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS 1655
VITAMINS 1655
VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12 1655
VITAMIN B-COMPLEX, INCL. COMBINATIONS 1656
MINERAL SUPPLEMENTS 1656
CALCIUM 1656
OTHER MINERAL SUPPLEMENTS 1657
BLOOD AND BLOOD FORMING ORGANS 1657
ANTITHROMBOTIC AGENTS 1657
ANTITHROMBOTIC AGENTS 1657
ANTIANEMIC PREPARATIONS 1658
IRON PREPARATIONS 1658
VITAMIN B12 AND FOLIC ACID 1658
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS 1659
IRRIGATING SOLUTIONS 1659
CARDIOVASCULAR SYSTEM 1659
VASOPROTECTIVES 1659
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE 1659
DERMATOLOGICALS 1659
ANTIFUNGALS FOR DERMATOLOGICAL USE 1659
ANTIFUNGALS FOR TOPICAL USE 1659
ANTIFUNGALS FOR SYSTEMIC USE 1660
EMOLLIENTS AND PROTECTIVES 1660
EMOLLIENTS AND PROTECTIVES 1660
PROTECTIVES AGAINST UV-RADIATION 1661
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. 1661
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. 1661
ANTIPSORIATICS 1661
ANTIPSORIATICS FOR TOPICAL USE 1661
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE 1661
ANTIBIOTICS FOR TOPICAL USE 1661
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS 1662

CORTICOSTEROIDS, PLAIN 1662
ANTISEPTICS AND DISINFECTANTS 1662
ANTISEPTICS AND DISINFECTANTS 1662
OTHER DERMATOLOGICAL PREPARATIONS 1663
OTHER DERMATOLOGICAL PREPARATIONS 1663

GENITO URINARY SYSTEM AND SEX HORMONES 1664

GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS 1664
ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS 1664
OTHER GYNECOLOGICALS 1665
OTHER GYNECOLOGICALS 1665
UROLOGICALS 1665
UROLOGICALS 1665
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY 1667

ANTIINFECTIVES FOR SYSTEMIC USE 1669

ANTIBACTERIALS FOR SYSTEMIC USE 1669
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS 1669

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 1669

ANTINEOPLASTIC AGENTS 1669
ANTIMETABOLITES 1669
IMMUNOSUPPRESSANTS 1670
IMMUNOSUPPRESSANTS 1670

MUSCULO-SKELETAL SYSTEM 1671

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN 1671
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN 1671
DRUGS FOR TREATMENT OF BONE DISEASES 1671
DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION 1671

NERVOUS SYSTEM 1672

ANALGESICS 1672
OPIOIDS 1672
OTHER ANALGESICS AND ANTIPYRETICS 1672
PSYCHOLEPTICS 1674
ANXIOLYTICS 1674
HYPNOTICS AND SEDATIVES 1674
OTHER NERVOUS SYSTEM DRUGS 1675
DRUGS USED IN ADDICTIVE DISORDERS 1675

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS 1675

ANTHELMINTICS 1675
ANTINEMATODAL AGENTS 1675

RESPIRATORY SYSTEM 1675

NASAL PREPARATIONS 1675

RPBS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE 1675
NASAL DECONGESTANTS FOR SYSTEMIC USE 1676
ANTIHISTAMINES FOR SYSTEMIC USE 1676
ANTIHISTAMINES FOR SYSTEMIC USE 1676

SENSORY ORGANS 1677

OPHTHALMOLOGICALS 1677
ANTIINFECTIVES 1677
OTOLOGICALS 1677
OTHER OTOLOGICALS 1677

VARIOUS 1677

ALL OTHER THERAPEUTIC PRODUCTS 1677
ALL OTHER THERAPEUTIC PRODUCTS 1677
GENERAL NUTRIENTS 1677
OTHER NUTRIENTS 1677
ALL OTHER NON-THERAPEUTIC PRODUCTS 1678
ALL OTHER NON-THERAPEUTIC PRODUCTS 1678

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE

chlorhexidine gluconate 0.2% mouthwash, 250 mL

4161B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	18.30	7.70	Plaqacide [OB]

chlorhexidine gluconate 0.2% mouthwash, 300 mL

4204G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.16	7.70	Savacol Mouth and Throat Rinse [OM]

NYSTATIN

nystatin 100 000 units/mL oral liquid, 24 mL

10854G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	1	..	19.94	7.70	[a] Pharmacy Action Nystatin Oral Drops [GQ]	[a] Trust Nystatin Oral Drops [CR]
		..	21.18	7.70	[a] Mycostatin Oral Drops [LN]	

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE

mebeverine hydrochloride 135 mg tablet, 90

4328T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	31.28	7.70	[a] APO-Mebeverine [TX]	[a] Colese [AF]
		..	35.78	7.70	[a] Colofac [GO]	

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

4279F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	20.52	7.70	[a] Buscopan [VZ]	[a] HYOSCINE BUTYLBROMIDE-AFT [AE]
					[a] HYOSCINE BUTYLBROMIDE MEDSURGE [DZ]	[a] HYOSCINE BUTYLBROMIDE SXP [XN]

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Softeners, emollients

DOCUSATE

docusate sodium 50 mg tablet, 100

4200C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	20.32	7.70	Coloxyl 50 [AS]

Contact laxatives

BISACODYL

bisacodyl 10 mg suppository, 10

10578R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*26.10	7.70	[a] Petrus Bisacodyl Suppositories [PP]
		..	*27.39	7.70	[a] Dulcolax [VZ]

RPBS

bisacodyl 10 mg suppository, 12

10580W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	4	..	*24.75	7.70	Petrus Bisacodyl Suppositories [PP]

▪ DOCUSATE + SENNOSIDE B

docusate sodium 50 mg + sennoside B 8 mg tablet, 90

10177P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	19.30	7.70	[a] Pharmacy Action Colox-Senna [HQ]	[a] Pharmacy Action Laxative with Senna [GQ]
		..	19.34	7.70	[a] Chemists' Own Laxative with Senna [RW]	[a] Colaxsen [AS]
					[a] Coloxyl with Senna [LN]	[a] Co-Senna [PP]
					[a] Trust Coloxease [CR]	

▪ SENNOSIDE B

sennoside B 7.5 mg tablet, 100

4455L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	18.86	7.70	[a] Senna-Gen [PP]
		..	19.93	7.70	[a] Senokot [RC]

Bulk-forming laxatives

▪ DRY PSYLLIUM HUSK

dry psyllium husk 3.5 g powder for oral liquid, 30 sachets

4285M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	23.22	7.70	Fybogel [RC]

▪ PSYLLIUM HUSK POWDER

psyllium husk powder 3.4 g/7 g powder for oral liquid, 504 g

12596Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	33.24	7.70	Metamucil Natural Granular [PY]

psyllium husk powder 3.4 g/5.9 g powder for oral liquid, 283 g

4419N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	26.72	7.70	Metamucil Orange Smooth [PY]

Enemas

▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 4 x 5 mL

4462W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	19.88	7.70	Micolette [AE]

Other drugs for constipation

▪ GLYCEROL

glycerol 1.4 g suppository, 12

10596Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*25.71	7.70	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 2.8 g suppository, 12

4246L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*26.19	7.70	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

10586E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*25.35	7.70	Petrus Pharmaceuticals Pty Ltd [PP]

▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

ANTIPROPULSIVES

Antipropulsives

RPBS

▪ LOPERAMIDE

loperamide hydrochloride 2 mg capsule, 12

10592L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	14.95	7.70	Gastrex [CR]

loperamide hydrochloride 2 mg capsule, 20

11135C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	15.26	7.70	[a] Gastrex [CR]	[a] Pharmacy Action Diarrhoea Relief [GQ]

▪ ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Peripherally acting antiobesity products

▪ ORLISTAT

Note The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

Authority required

Obesity

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

Authority required

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their inital body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Authority required

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their inital body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

orlistat 120 mg capsule, 84

4570M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	136.12	7.70	Xenical [PB]

▪ VITAMINS

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

▪ THIAMINE

thiamine hydrochloride 100 mg tablet, 100

4043T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17.35	7.70	Betavit [PP]

▪ THIAMINE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

thiamine hydrochloride 100 mg tablet, 100

14182K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*21.25	7.70	Betavit [PP]

VITAMIN B-COMPLEX, INCL. COMBINATIONS

Vitamin B-complex, plain

▪ LYSINE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + FERRIC PYROPHOSPHATE

lysine hydrochloride 300 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL oral liquid, 200 mL

4493L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	19.48	7.70	Accomin Adult Tonic [PF]

▪ MINERAL SUPPLEMENTS

CALCIUM

Calcium

▪ CALCIUM

Restricted benefit

Hyperphosphataemia

Clinical criteria:

- The condition must be associated with chronic renal failure.

calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

4142B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*24.61	7.70	[a] Cal-care 600 mg [CR]
		..	*27.25	7.70	[a] CAL-600 [PP]

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

11845K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*29.55	7.70	Cal-500 [PP]

▪ CALCIUM

Restricted benefit

Hyperphosphataemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be associated with chronic renal failure.

calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

14175C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	1	..	*35.75	7.70	[a] Cal-care 600 mg [CR]
		..	*41.03	7.70	[a] CAL-600 [PP]

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

14217G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	1	..	*45.63	7.70	Cal-500 [PP]

▪ CALCIUM

Restricted benefit

Hypocalcaemia

Restricted benefit

Osteoporosis

Restricted benefit

Proven calcium malabsorption

calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

4082W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	19.03	7.70	[a] Cal-care 600 mg [CR]
		..	20.35	7.70	[a] CAL-600 [PP]

RPBS

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

11862H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	21.50	7.70	Cal-500 [PP]

▪ CALCIUM

Restricted benefit

Hypocalcaemia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Osteoporosis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Proven calcium malabsorption

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

14174B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*24.61	7.70	[a] Cal-care 600 mg [CR]
		..	*27.25	7.70	[a] CAL-600 [PP]

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

14176D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*29.55	7.70	Cal-500 [PP]

OTHER MINERAL SUPPLEMENTS

Magnesium

▪ MAGNESIUM

Restricted benefit

Hypomagnesaemia

The condition must be documented in the patient's medical records.

magnesium 37.4 mg tablet, 50

4321K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	19.19	7.70	Mag-Sup [PP]	
		..	19.48	7.70	Amcal Mag-A [IG]	Pharmacy Care Magnesium [SI]
		..	20.05	7.70	Magmin [BB]	

▪ BLOOD AND BLOOD FORMING ORGANS

▪ ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Platelet aggregation inhibitors excl. heparin

▪ ASPIRIN

aspirin 100 mg tablet, 112

10590J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	15.58	7.70	Spren 100 [OW]

aspirin 100 mg tablet, 90

4076M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	21.50	7.70	Cardiprin 100 [RC]

▪ ASPIRIN

Note The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

aspirin 100 mg enteric capsule, 84

4078P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	20.59	7.70	Astrix [YN]

aspirin 100 mg enteric tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4077N	1	1	..	19.80	7.70	Cardasa [AF] [a] Cartia [AS] [a] Trust Aspirin EC 100 [CR]	[a] Pharmacy Action Low Dose Aspirin [GQ]

▪ CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Authority required

For use in patients pre- and post-angioplasty

clopidogrel 75 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10169F	1	3	..	17.55	7.70	[a] BTC Clopidogrel [JB]	[a] Plidogrel [RF]

clopidogrel 75 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4179Y	1	3	..	17.55	7.70	[a] Clopidogrel Lupin [GQ] [a] Iscover [AV] [a] Plavicor 75 [CR]	[a] Clopidogrel Sandoz Pharma [HX] [a] Piax [AF]

▪ ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

▪ FERROUS FUMARATE

ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10594N	1	1	..	19.79	7.70	Ferro-tab [AE]

Iron in combination with folic acid

▪ FERROUS FUMARATE + FOLIC ACID

ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10579T	1	1	..	20.76	7.70	Ferro-f-tab [AE]

VITAMIN B12 AND FOLIC ACID

Vitamin B12 (cyanocobalamin and analogues)

▪ HYDROXOCOBALAMIN

Note One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B_{12} deficiencies.

Note Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

Restricted benefit

Pernicious anaemia

Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

Restricted benefit

Anaemias associated with vitamin B12 deficiency

Clinical criteria:

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10577Q	1	..	..	17.84	7.70	[a] Vita-B12 [GH]

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10587F	1	..	..	17.84	7.70	[a] Neo-B12 [PF]

Folic acid and derivatives

▪ FOLIC ACID

folic acid 500 microgram tablet, 100

10584C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*17.67	7.70	[a] Foltabs 500 [PP]	[a] Megafol 0.5 [AF]

▪ FOLIC ACID

Note The 5 mg strength tablet should be used in malabsorption states only.

folic acid 5 mg tablet, 100

10573L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*19.75	7.70	Megafol 5 [AF]

▪ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

IRRIGATING SOLUTIONS

Salt solutions

▪ SODIUM CHLORIDE

sodium chloride 0.9% (9 g/L) solution, 1 L bottle

4461T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	17.29	7.70	Baxter Healthcare Pty Ltd [BX]

sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle

4460R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	17.03	7.70	Baxter Healthcare Pty Ltd [BX]

▪ CARDIOVASCULAR SYSTEM

▪ VASOPROTECTIVES

AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

Other agents for treatment of hemorrhoids and anal fissures for topical use

▪ ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g

4039N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	20.43	7.70	Anusol [JT]

zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12

4040P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	19.49	7.70	Anusol [JT]

▪ DERMATOLOGICALS

▪ ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Imidazole and triazole derivatives

▪ CLOTRIMAZOLE

clotrimazole 1% cream, 20 g

4004R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	15.51	7.70	[a] Pharmacy Action Anti-Fungal Cream [GQ]
		..	15.82	7.70	[a] Clonea [AF]

Other antifungals for topical use

▪ AMOROLFINE

Restricted benefit
Onychomycosis

amorolfine 5% solution, 5 mL

4010C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	1	..	50.02	7.70	[a] Myconail [AE]	[a] Pharmacy Action Anti-Fungal Nail Treatment [GQ]
		..	86.27	7.70	[a] Aporyl [TX]	
		..	95.02	7.70	[a] Loceryl [GA]	

RPBS

▪ TERBINAFINE

Restricted benefit

Tinea pedis

terbinafine 1% gel, 15 g

4463X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	28.18	7.70	Lamisil DermGel [NP]

terbinafine hydrochloride 1% cream, 15 g

4473K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	1	..	26.91	7.70	[a] Lamisil [NP]	[a] Pharmacy Action Pharmisil [GQ]
					[a] Trust Terbinafine Cream [CR]	

▪ TOLNAFTATE

tolnaftate 0.07% spray, 100 g

4481W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.00	7.70	Tinaderm [BN]

ANTIFUNGALS FOR SYSTEMIC USE

Antifungals for systemic use

▪ TERBINAFINE

Authority required

Onychomycosis

Clinical criteria:

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

terbinafine 250 mg tablet, 42

4011D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	28.82	7.70	[a] APO-Terbinafine [TX]	[a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
					[a] Tamsil [RW]	[a] Terbinafine Sandoz [SZ]
					[a] Tinasil [AF]	

▪ EMOLLIENTS AND PROTECTIVES

EMOLLIENTS AND PROTECTIVES

Soft paraffin and fat products

▪ WOOL ALCOHOLS

wool alcohols 6% ointment, 100 g

4041Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	20.21	7.70	Eucerin [BE]

Carbamide products

▪ UREA

urea 10% cream, 100 g

4042R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	18.54	7.70	Aquacare H.P. [VE]
		..	18.74	7.70	Urederm [KY]

Other emollients and protectives

▪ GELATIN + PECTIN + CARMELLOSE SODIUM

gelatin 16.7% + pectin 16.7% + carmellose sodium 16.7% paste, 5 g

4518T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	18.26	7.70	Orabase [AS]

▪ GLYCEROL + WHITE SOFT PARAFFIN

glycerol 5% + white soft paraffin 5% lotion, 1 L

11712K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	32.66	7.70	QV Skin Lotion [EO]

▪ SKIN EMOLLIENT

SKIN EMOLLIENT Bath oil 500 mL, 1

4122Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	22.96	7.70	Alpha Keri Bath Oil [MT]
			..	25.06	7.70	QV Bath Oil [EO]
			..	25.14	7.70	Hamilton Skin Therapy Oil [KY]

SKIN EMOLLIENT Lotion 500 mL, 1

4107E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	22.96	7.70	Alpha Keri Lotion [MT]

PROTECTIVES AGAINST UV-RADIATION

Protectives against UV-radiation for topical use

▪ BEMOTRIZINOL + DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE + HOMOSALATE + OCTOCRYLENE + TITANIUM DIOXIDE

bemotrizinol 1.8% + diethylamino hydroxybenzoyl hexyl benzoate 4% + homosalate 8% + octocrylene 8% + titanium dioxide 2.5% lotion, 125 mL

13188D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	23.57	7.70	Sunsense Comfort SPF 50+ [EO]

▪ SUNSCREENS

SUNSCREENS Cream 75 g, 1

4307Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	23.57	7.70	Sunsense Sensitive SPF 50+ [EO]

SUNSCREENS Lotion (non-alcoholic) 125 mL, 1

4546G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	21.77	7.70	Aquasun Lotion SPF 18 [PF]

▪ ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

Anesthetics for topical use

▪ LIDOCAINE

lidocaine hydrochloride 2% oral liquid, 200 mL

4308R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	105.58	7.70	Xylocaine Viscous [AS]

Other antipruritics

▪ TAR + TROLAMINE LAURIL SULFATE

Note For patients who have failed to respond to simple moisturising agents.

tar 2.3% + trolamine lauril sulfate 6% solution, 500 mL

4408B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	27.81	7.70	Pinetarsol [EO]

▪ ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars

▪ COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g

4505D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	21.81	7.70	Egopsoryl-TA [EO]

▪ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

ANTIBIOTICS FOR TOPICAL USE

Other antibiotics for topical use

▪ MUPIROCIN

mupirocin 2% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4350Y	‡1	..	..	22.08	7.70	[a] Medicianz Mupirocin Ointment [DZ]
			..	22.88	7.70	[a] APO-Mupirocin [TX]
			..	25.95	7.70	[a] Bactroban [GK]

▪ MUPIROCIN

Restricted benefit

Secondarily infected traumatic skin lesions

mupirocin 2% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4348W	‡1	..	..	25.95	7.70	[a] Bactroban [GK]	[a] SUPIROCIN [JM]

▪ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, weak (group I)

▪ HYDROCORTISONE ACETATE

hydrocortisone acetate 1% cream, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11710H	‡1	1	..	18.68	7.70	[a] Pharmacy Action Hydrocortisone Cream 1% [GQ]	[a] Trust HydroCortic Cream [CR]

▪ HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% ointment, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10831C	‡1	1	..	18.68	7.70	Cortic-DS 1% [AS]

Corticosteroids, potent (group III)

▪ BETAMETHASONE VALERATE

betamethasone (as valerate) 0.1% cream, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4131K	‡1	2	..	27.38	7.70	Betnovate [AS]

betamethasone (as valerate) 0.1% ointment, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4132L	‡1	2	..	27.38	7.70	Betnovate [AS]

▪ MOMETASONE

Note Application to large areas of skin for longer than four weeks is not recommended.

mometasone furoate 0.1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4342M	‡1	..	..	36.99	7.70	Elocon Alcohol Free [AL]

mometasone furoate 0.1% ointment, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4343N	‡1	..	..	36.99	7.70	Elocon [AL]

RPBS

▪ ANTISEPTICS AND DISINFECTANTS

ANTISEPTICS AND DISINFECTANTS

Iodine products

▪ POVIDONE-IODINE

povidone-iodine 10% solution, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4411E	‡1	..	..	27.10	7.70	Betadine Antiseptic Liquid [SW]

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Medicated shampoos

COAL TAR SOLUTION + SALICYLIC ACID

coal tar solution 4.25% + salicylic acid 2% shampoo, 200 mL

4560B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	25.60	7.70	Ionil-T [GA]

SELENIUM SULFIDE

selenium sulfide 2.5% shampoo, 125 mL

4452H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.17	7.70	Selsun [DQ]

TAR + COAL TAR SOLUTION + SALICYLIC ACID

tar 1% + coal tar solution 1% + salicylic acid 2% solution, 250 mL

4447C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	24.26	7.70	Sebitar [EO]

Wart and anti-corn preparations

SALICYLIC ACID + LACTIC ACID

salicylic acid 16.7% + lactic acid 15% solution, 15 mL

11959K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	23.66	7.70	Duofilm Solution [GK]

Other dermatologicals

DICLOFENAC

Note Maximum quantity of four tubes (original + 3 repeats) in 12 months.

Authority required

Solar (actinic) keratosis

Treatment Phase: Management

Clinical criteria:

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

diclofenac sodium 3% gel, 25 g

4046Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	63.02	7.70	Solaraze 3% Gel [YN]

GLYCEROL

glycerol 15% solution, 1 kg

11708F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	32.17	7.70	QV Gentle Wash [EO]

ICHTHAMMOL

Note For patients who have failed to respond to simple moisturising agents.

ichthammol 1% cream, 50 g

4281H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	23.62	7.70	Egoderm Cream [EO]

ICHTHAMMOL + ZINC OXIDE

Note For patients who have failed to respond to simple moisturising agents.

ichthammol 1% + zinc oxide 15% ointment, 50 g

4280G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	23.62	7.70	Egoderm Ointment [EO]

IMIQUIMOD

Authority required

Superficial basal cell carcinoma

Treatment Phase: Primary treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The condition must be one where other standard treatments are inappropriate, **AND**
- The condition must require topical drug therapy.

imiquimod 5% cream, 12 x 250 mg sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4559Y	1	1	..	88.99	7.70	[a] Aldiq [AF]	[a] APO-Imiquimod [TX]
			..	92.29	7.70	[a] Aldara [IL]	

▪ IMIQUIMOD

Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required

Solar keratosis

Clinical criteria:

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

imiquimod 5% cream, 12 x 250 mg sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4134N	1	1	..	88.99	7.70	[a] Aldiq [AF]	[a] APO-Imiquimod [TX]
			..	92.29	7.70	[a] Aldara [IL]	

imiquimod 5% cream, 2 x 2 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10106X	1	1	..	97.34	7.70	[a] Aldara Pump [IL]

▪ LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4549K	‡1	2	..	25.91	7.70	Hamilton Skin Therapy Wash [KY]

▪ PANTHENOL

Note To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

panthenol conditioner, 200 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4510J	‡1	2	..	20.27	7.70	SebiRinse [EO]

▪ ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN

zinc oxide 25% + maize starch 55.85% + purified talc 18.07% + chlorphenesin 1% powder, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4497Q	‡1	1	..	18.59	7.70	Z.S.C. [RW]

▪ GENITO URINARY SYSTEM AND SEX HORMONES

▪ GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

Antibiotics

RPBS

▪ NYSTATIN

nystatin 20 000 units/g vaginal cream, 75 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4013F	‡1	1	..	19.87	7.70	Nilstat [AS]

Imidazole derivatives

▪ CLOTRIMAZOLE

clotrimazole 2% vaginal cream, 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4017K	‡1	..	..	20.99	7.70	[a] APO-Clotrimazole 3 Day Cream [TX]	[a] Clonea 3 Day Cream [AF]
						[a] Pharmacy Action FemCream 3 Day Cream [GQ]	[a] Trust Fem V 3 Day Cream [CR]

clotrimazole 1% vaginal cream, 35 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4016J	‡1	..	..	19.78	7.70	[a] Clonea 6 Day Cream [AF]	[a] Pharmacy Action FemCream [GQ]
						[a] Trust Fem V 6 Day Cream [CR]	
			..	20.99	7.70	[a] APO-Clotrimazole 6 Day Cream [TX]	

▪ OTHER GYNECOLOGICALS

OTHER GYNECOLOGICALS

▪ ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4434J	‡1	..	..	36.49	7.70	Aci-Jel [CU]

▪ UROLOGICALS

UROLOGICALS

Drugs used in erectile dysfunction

▪ ALPROSTADIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

alprostadil 10 microgram injection [1 chamber] (&) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4579B	3	3	..	*120.66	7.70	Caverject Impulse [PF]

alprostadil 20 microgram injection [1 chamber] (&) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4580C	3	3	..	*152.97	7.70	Caverject Impulse [PF]

▪ AVANAFIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

avanafil 100 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11861G	1	5	..	54.32	7.70	Spedra [FK]

avanafil 200 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11860F	1	5	..	56.47	7.70	Spedra [FK]

avanafil 50 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11837B	1	5	..	52.17	7.70	Spedra [FK]

▪ SILDENAFIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

sildenafil 100 mg tablet, 4

4586J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	33.46	7.70	[a] Sildenafil generichealth [GQ]	[a] Sildenafil Lupin [HQ]
					[a] Viagra [UJ]	
		..	73.98	7.70	[a] NOUMED Sildenafil [VO]	[a] Sildenafil APOTEX [GX]
					[a] Sildenafil Sandoz [SZ]	[a] Vasafil 100 [RW]
					[a] Vedafil [AF]	

sildenafil 25 mg tablet, 4

4584G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	26.53	7.70	[a] Viagra [UJ]	
		..	57.41	7.70	[a] Sildenafil APOTEX [GX]	[a] Sildenafil Sandoz [SZ]
					[a] Vasafil 25 [RW]	[a] Vedafil [AF]

sildenafil 50 mg tablet, 4

4585H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	30.10	7.70	[a] Sildenafil Lupin [HQ]	[a] Viagra [UJ]
		..	69.41	7.70	[a] NOUMED Sildenafil [VO]	[a] Sildenafil APOTEX [GX]
					[a] Sildenafil Sandoz [SZ]	[a] Vasafil 50 [RW]
					[a] Vedafil [AF]	

▪ TADALAFIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

tadalafil 10 mg tablet, 4

4596X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	106.22	7.70	[a] Apo-Tadalafil [TX]	[a] Cialis [LY]
					[a] Cidala [RW]	[a] Cilatil [AF]
					[a] Cipla Tadalafil [LR]	[a] Tadalafil GH [GQ]
					[a] Tadalafil Sandoz [SZ]	

tadalafil 20 mg tablet, 4

4597Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	106.22	7.70	[a] Apo-Tadalafil [TX]	[a] Cialis [LY]
					[a] Cidala [RW]	[a] Cilatil [AF]
					[a] Cipla Tadalafil [LR]	[a] Tadalaccord [CR]
					[a] Tadalafil GH [GQ]	[a] Tadalafil Sandoz [SZ]

Other urologicals

▪ BICARBONATE + CITRIC ACID + TARTARIC ACID

Note Pharmaceutical benefits that have the forms sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid and sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules are equivalent for the purposes of substitution.

Restricted benefit

Urinary symptoms

Clinical criteria:

- The treatment must be for when antibiotic or other therapy alone is inappropriate.

RPBS

sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets

4049D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	4	..	19.66	7.70	[a] Pharmacy Action Cystitis Relief [GQ]	[a] Ural Sachets [AS]

sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules, 28 x 4 g sachets

12179B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	4	..	19.66	7.70	[a] Trust Cystitis Relief [CR]

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

▪ ALFUZOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms.

alfuzosin hydrochloride 10 mg modified release tablet, 30

4277D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	77.03	7.70	Xatral SR [SW]

▪ ALFUZOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

alfuzosin hydrochloride 10 mg modified release tablet, 30

14183L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*141.95	7.70	Xatral SR [SW]

▪ DUTASTERIDE + TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

10102Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	34.86	7.70	Duodart 500ug/400ug [GK]

▪ DUTASTERIDE + TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

14184M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*56.27	7.70	Duodart 500ug/400ug [GK]

▪ SILODOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms.

silodosin 8 mg capsule, 30

12077P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	45.00	7.70	Urorec [YN]

silodosin 4 mg capsule, 30

12079R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	40.25	7.70	Urorec [YN]

▪ SILODOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

silodosin 8 mg capsule, 30

14192Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*76.55	7.70	Urorec [YN]

silodosin 4 mg capsule, 30

14185N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*67.05	7.70	Urorec [YN]

▪ TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms.

tamsulosin hydrochloride 400 microgram modified release tablet, 30

4070F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	65.22	7.70	[a] Apo-Tamsulosin SR [TX]	[a] Blooms the Chemist Tamsulosin SR [IB]
					[a] BTC Tamsulosin SR [BG]	[a] Flomaxtra [LS]
					[a] Flosix [AF]	[a] Tamsulosin Lupin SR [GQ]
					[a] Tamsulosin Sandoz SR [SZ]	

▪ TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

tamsulosin hydrochloride 400 microgram modified release tablet, 30

14200J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*117.15	7.70	[a] Apo-Tamsulosin SR [TX]	[a] Blooms the Chemist Tamsulosin SR [IB]
					[a] BTC Tamsulosin SR [BG]	[a] Flomaxtra [LS]
					[a] Flosix [AF]	[a] Tamsulosin Sandoz SR [SZ]

Testosterone-5-alpha reductase inhibitors

▪ DUTASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms.

dutasteride 500 microgram capsule, 30

10095H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	29.82	7.70	[a] APO-Dutasteride [TX]
		..	36.82	7.70	[a] Avodart [GK]

▪ DUTASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

dutasteride 500 microgram capsule, 30

14210X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*46.19	7.70	[a] APO-Dutasteride [TX]
		..	*60.19	7.70	[a] Avodart [GK]

▪ FINASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms.

finasteride 5 mg tablet, 28

4303L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	90.59	7.70	Finpro [RZ]

finasteride 5 mg tablet, 30

4233T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	78.25	7.70	[a] Finasteride GH 5 [GQ]	[a] Finasteride Mylan 5 [AF]
					[a] Finide [AL]	
		..	96.10	7.70	[a] Finnacar [RW]	
		..	100.45	7.70	[a] APO-Finasteride [TX]	[a] Finasta [SZ]
					[a] Finasteride-GA 5 [GN]	[a] Pharmacor Finasteride 5 [CR]
					[a] Proscar [OQ]	

▪ FINASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

finasteride 5 mg tablet, 28

14191X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*170.43	7.70	Finpro [RZ]

finasteride 5 mg tablet, 30

14199H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*144.51	7.70	[a] Finasteride GH 5 [GQ]	[a] Finasteride Mylan 5 [AF]
					[a] Finide [AL]	
		..	*182.01	7.70	[a] Finnacar [RW]	
		..	*191.13	7.70	[a] APO-Finasteride [TX]	[a] Finasta [SZ]
					[a] Finasteride-GA 5 [GN]	[a] Pharmacor Finasteride 5 [CR]
					[a] Proscar [OQ]	

▪ ANTIINFECTIVES FOR SYSTEMIC USE

▪ ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

▪ AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections

azithromycin 500 mg tablet, 3

4115N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	35.28	7.70	Zedd 500 [RW]	
					[a] APO-Azithromycin [TX]	[a] Azithromycin Mylan [AF]
					[a] Azithromycin Sandoz [SZ]	[a] ZITHRO [RF]
					[a] Zithromax [PF]	

▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

▪ ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

RPBS

▪ FLUOROURACIL

fluorouracil 4% cream, 20 g

13758D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	68.30	7.70	TOLAK 4% ONCE DAILY [AS]

fluorouracil 5% cream, 20 g

4222F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	..	..	67.65	7.70	[a] APOC-5FU [TX]	[a] Fluorouracil Viatris [AF]
		..	76.68	7.70	[a] Efudix [IL]	

▪ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Tumor necrosis factor alpha (TNF-alpha) inhibitors

▪ INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab, or requests for forms, may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.
Written applications for authority to prescribe infliximab should be forwarded to:
Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

Authority required

Rheumatoid arthritis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

Population criteria:

- Patient must be an adult.

Clinical criteria:

- Patient must have active rheumatoid arthritis, **AND**
- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have a proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP) level, **AND**
- Patient must have proven erosive rheumatoid arthritis without end-stage disease, **AND**
- Patient must have failed an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or ciclosporin), unless these drugs were contraindicated or intolerance developed, **AND**
- Patient must have no history of active tuberculosis requiring treatment in the last 3 years, **AND**
- Patient must have no history of opportunistic infection in the last 2 months, **AND**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must be for the reduction of signs and symptoms and prevention of structural joint damage, **AND**
- Patient must not be pregnant or breastfeeding, **AND**
- Patient must be using an effective form of contraception if female and of child-bearing age.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

Authority required

Rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have previously been issued with an authority prescription for this drug for the treatment of this condition, **AND**
- Patient must have demonstrated an improvement in ESR and/or CRP level following the initial 3 dose course of therapy, **AND**
- Patient must have achieved an ACR20 (American College of Rheumatology) response by 14 weeks after the commencement of the initial course of therapy, **AND**
- The treatment must be in combination with methotrexate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

infliximab 100 mg injection, 1 vial

4284L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	215.30	7.70	Remicade [JC]

MUSCULO-SKELETAL SYSTEM

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

Preparations with salicylic acid derivatives

METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM EXTRACT

methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum extract 0.15% cream, 100 g

11707E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	20.07	7.70	Goanna Heat Cream [GQ]

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

RISEDRONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

risedronate sodium 35 mg tablet, 4

4444X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	33.88	7.70	[a] APO-Risedronate [TX] [a] Risedronate Sandoz [SZ]	[a] Risedronate-GA [GN]

risedronate sodium 35 mg enteric tablet, 4

2191H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	33.88	7.70	Actonel EC [TT]

risedronate sodium 5 mg tablet, 28

4443W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.47	7.70	Actonel [TT]

RISEDRONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

risedronate sodium 35 mg tablet, 4

14197F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*54.31	7.70	[a] APO-Risedronate [TX] [a] Risedronate Sandoz [SZ]	[a] Risedronate-GA [GN]

risedronate sodium 35 mg enteric tablet, 4

14198G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*54.31	7.70	Actonel EC [TT]

risedronate sodium 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14209W	2	5	..	*61.49	7.70	Actonel [TT]

Bisphosphonates, combinations

▪ ALENDRONATE + COLECALCIFEROL

Authority required

Preservation of bone mineral density

Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2224C	1	5	..	18.98	7.70	Fosamax Plus 70 mg/140 mcg [MQ]

alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2194L	1	5	..	18.98	7.70	Fosamax Plus [MQ]

▪ NERVOUS SYSTEM

▪ ANALGESICS

OPIOIDS

Natural opium alkaloids

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 200 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4349X	1	..	..	121.43	7.70	MS Contin [MF]

Opioids in combination with non-opioid analgesics

▪ ASPIRIN + CODEINE

aspirin 300 mg + codeine phosphate hemihydrate 8 mg dispersible tablet, 40

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4286N	1	2	..	20.21	7.70	Aspalgin 40 [GO]

▪ PARACETAMOL + CODEINE

paracetamol 500 mg + codeine phosphate hemihydrate 8 mg tablet, 40

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4275B	1	2	..	18.98	7.70	Panamax Co. 40 [SW]

OTHER ANALGESICS AND ANTIPYRETICS

Anilides

▪ PARACETAMOL

paracetamol 48 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10599W	‡1	2	..	17.31	7.70	[a] Panamax 240 Elixir [SW]	[a] Trust for Kids Paracetamol 6 to 12 years [CR]

RPBS

paracetamol 500 mg tablet, 100

10582Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	15.13	7.70	[a] APO-Paracetamol [TX] [a] Panamax [SW] [a] Paracetamol Sandoz Pharma [QS] [a] Parapane [AF] [a] Wagner Health Paracetamol [BG]	[a] Febridol [XT] [a] Paracetamol (Sandoz) [SZ] [a] Paralgin [OW] [a] PHARMACY CARE PARACETAMOL [SI]

▪ PARACETAMOL

Restricted benefit

Persistent pain

Clinical criteria:

- The condition must be associated with osteoarthritis.

paracetamol 665 mg modified release tablet, 96

10598T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*20.99	7.70	[a] Osteomol 665 Paracetamol [CR] [a] Pharmacy Action OSTEO Relief 665 [HQ]	[a] Parapane OSTEO [AF] [a] Pharmacy Action Paracetamol Osteo 665 [GQ]

▪ PARACETAMOL

Restricted benefit

Chronic arthropathies

paracetamol 500 mg tablet, 100

10585D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	4	..	*18.48	7.70	[a] APO-Paracetamol [TX] [a] Panamax [SW] [a] Paracetamol Sandoz Pharma [QS] [a] Parapane [AF] [a] Wagner Health Paracetamol [BG]	[a] Febridol [XT] [a] Paracetamol (Sandoz) [SZ] [a] Paralgin [OW] [a] PHARMACY CARE PARACETAMOL [SI]

Gabapentinoids

▪ GABAPENTIN

Authority required

Refractory neuropathic pain

Clinical criteria:

- The condition must be unable to be controlled by other drugs.

gabapentin 100 mg capsule, 100

4591P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.63	7.70	[a] APX-Gabapentin [GX] [a] Neurontin [UJ]	[a] Gabacor [CR] [a] Nupentin 100 [AF]

gabapentin 300 mg capsule, 100

4592Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	24.95	7.70	[a] APX-Gabapentin [GX] [a] Gabapentin generichealth [HQ] [a] Neurontin [UJ]	[a] Gabacor [CR] [a] Gabapentin Sandoz [SZ] [a] Nupentin 300 [AF]

gabapentin 400 mg capsule, 100

4593R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	29.13	7.70	[a] APX-Gabapentin [GX] [a] Gabapentin generichealth [HQ] [a] Neurontin [UJ]	[a] Gabacor [CR] [a] Gabapentin Sandoz [SZ] [a] Nupentin 400 [AF]

gabapentin 600 mg tablet, 100

4594T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	38.32	7.70	[a] Gabapentin APOTEX [TY] [a] Pharmacor Gabapentin 600 [CR]	[a] Neurontin [UJ]

gabapentin 800 mg tablet, 100

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	46.61	7.70	[a] Gabapentin APOTEX [TY]	[a] Neurontin [UJ]

4595W	[a] Pharmacor Gabapentin 800 [CR]

PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

BROMAZEPAM

Note This drug should not be used as the first line of treatment.
Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.
Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required
Terminal disease
Clinical criteria:
- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

Authority required
Refractory phobic or anxiety states
Clinical criteria:
- The treatment must be for the short-term.

bromazepam 3 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4150K	2	..	..	*33.53	7.70	Lexotan [PB]

bromazepam 6 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4151L	2	..	..	*39.27	7.70	Lexotan [PB]

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

FLUNITRAZEPAM

Note This drug should not be used as the first line of treatment.
Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.
Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required
Terminal disease
Clinical criteria:
- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

Authority required
Refractory phobic or anxiety states
Clinical criteria:
- The treatment must be for the short-term.

flunitrazepam 1 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4216X	1	..	..	23.89	7.70	Hypnodorm [AF]

Benzodiazepine related drugs

ZOPICLONE

Restricted benefit
Insomnia
Clinical criteria:
- The treatment must be for the short-term.

zopiclone 7.5 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13307J	1	1	..	22.35	7.70	Imovane [SW]

zopiclone 7.5 mg tablet, 30

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	26.80	7.70	[a] APO-Zopiclone [TX]	[a] Imoclone [RW]

RPBS

4522B					[a] Imrest [AF]	[a] Pharmacor Zopiclone [CR]
					[a] Zopiclone GH [GQ]	
		..	29.54	7.70	[a] Imovane [SW]	

OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

NICOTINE

Note Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

Authority required

Nicotine dependence

Clinical criteria:

- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

nicotine 14 mg/24 hours patch, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4572P	2	..	..	*57.11	7.70	QuitX [AF]

nicotine 21 mg/24 hours patch, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4573Q	2	2	..	*60.07	7.70	QuitX [AF]

nicotine 7 mg/24 hours patch, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4571N	2	..	..	*53.95	7.70	QuitX [AF]

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

ANTHELMINTICS

ANTINEMATODAL AGENTS

Benzimidazole derivatives

MEBENDAZOLE

Note Pharmaceutical benefits that have the forms mebendazole 100 mg tablet and mebendazole 100 mg chewable tablet are equivalent for the purposes of substitution.

mebendazole 100 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4325P	1	..	..	19.66	7.70	[a] Pharmacy Action Worm Treatment [GQ]

mebendazole 100 mg chewable tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12194T	1	..	..	19.66	7.70	[a] Trust Deworm [CR]

RESPIRATORY SYSTEM

NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Sympathomimetics, plain

OXYMETAZOLINE

oxymetazoline hydrochloride 0.05% nasal spray, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4378K	‡1	..	..	22.79	7.70	Drixine [BN]

oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4379L	‡1	..	..	22.45	7.70	Logicin Rapid Relief [AS]

oxymetazoline hydrochloride 0.05% nasal spray, 20 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11711J	‡1	..	..	22.45	7.70	[a] Pharmacy Action Nasal Decongestant [GQ]	[a] Trust Decongestant Nasal Spray [CR]

Antiallergic agents, excl. corticosteroids

▪ CROMOGLYCATE

sodium cromoglycate 2% nasal spray, 26 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4468E	‡1	5	..	27.80	7.70	Rynacrom [SW]

Corticosteroids

▪ BUDESONIDE

Restricted benefit

Severe intractable rhinitis

budesonide 64 microgram/actuation nasal spray, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4092J	‡1	..	..	44.05	7.70	Budamax Aqueous [JT]

NASAL DECONGESTANTS FOR SYSTEMIC USE

Sympathomimetics

▪ PSEUDOEPHEDRINE

pseudoephedrine hydrochloride 60 mg tablet, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4029C	1	..	..	16.99	7.70	[a] Pharmacy Action Sinus & Nasal Decongestant Relief [GQ]	[a] Trust Sinus & Nasal Decongestant [CR]

▪ ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

Piperazine derivatives

▪ CETIRIZINE

cetirizine hydrochloride 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4175R	1	..	..	30.43	7.70	[a] Pharmacy Action Cetrelief [GQ]	[a] Trust Cetirizine [CR]
			..	33.66	7.70	[a] Alzene [AF]	

Other antihistamines for systemic use

▪ FEXOFENADINE

fexofenadine hydrochloride 120 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4238C	1	..	..	30.25	7.70	[a] Pharmacy Action Fexorelief 120 [GQ]	[a] Trust Fexit 120 [CR]
			..	33.46	7.70	[a] Xergic [AF]	
			..	49.67	7.70	[a] Telfast 120 [SW]	

fexofenadine hydrochloride 60 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4237B	3	..	..	*57.54	7.70	Telfast [SW]

▪ LORATADINE

loratadine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4313B	1	..	..	32.86	7.70	[a] Pharmacy Action Lorastyne [GQ] [a] Trust Loratadine Antihistamine [RM]	[a] Trust Loratadine [CR]
			..	36.56	7.70	[a] Allereze [AF]	
			..	48.46	7.70	[a] Claratyne [BN]	

RPBS

SENSORY ORGANS

OPHTHALMOLOGICALS

ANTIINFECTIVES

Antibiotics

CHLORAMPHENICOL

chloramphenicol 0.5% eye drops, 10 mL

14180H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	17.57	7.70	Chlorsig [AS]

OTOLOGICALS

OTHER OTOLOGICALS

Indifferent preparations

CARBAMIDE PEROXIDE

carbamide peroxide 6.5% ear drops, 12 mL

4176T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	22.94	7.70	Ear Clear for Ear Wax Removal [KY]

DOCUSATE

docusate sodium 0.5% ear drops, 10 mL

4199B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.46	7.70	Waxsol [GO]

ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL

ortho-dichlorobenzene 14% + para-dichlorobenzene 2% + chlorobutanol hemihydrate 5% + arachis oil 57% ear drops, 10 mL

4180B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.12	7.70	Cerumol [UN]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Drugs for treatment of hyperkalemia and hyperphosphatemia

SODIUM POLYSTYRENE SULFONATE

sodium polystyrene sulfonate 999.3 mg/g powder, 454 g

4470G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	83.15	7.70	Resonium-A [SW]

GENERAL NUTRIENTS

OTHER NUTRIENTS

Other combinations of nutrients

PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC

Restricted benefit

Stage 2 and above pressure injury

Clinical criteria:

- The treatment must be for special medical purposes to support healing of pressure injuries.

protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 200 mL bottles

11401C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*207.33	7.70	Cubitan [SB]

ALL OTHER NON-THERAPEUTIC PRODUCTS

ALL OTHER NON-THERAPEUTIC PRODUCTS

LUBRICATING AGENT

lubricating agent gel, 100 g

4306P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	16.87	7.70	Lubri-Gel [PP]

Other non-therapeutic auxiliary products

BANDAGE ABSORBENT WOOL

bandage absorbent wool 10 cm x 3 m bandage, 1

4653X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	25.55	7.70	Surepress 650948 [CC]

BANDAGE CALICO

bandage calico large triangular bandage, 1

4717G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	19.47	7.70	Handy 36361414 [BV]

BANDAGE COMPRESSION

bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack

11714M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	40.05	7.70	Rosidal TCS 26484 [LC]

BANDAGE COMPRESSION

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

bandage compression two layer bandage, 1

12592R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	53.15	7.70	Putter Pro 2 931685 [HR]

BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

bandage compression 10 cm x 3 m high stretch bandage, 1

4748X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*73.92	7.70	Surepress 650947 [CC]
		..	*154.17	7.70	Tensopress 71723-00 [BV]

bandage compression 8 cm x 2.6 m short stretch bandage, 1

4654Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*79.27	7.70	Comprilan 01027-00 [BV]

BANDAGE COMPRESSION

Note Use with caution if arterial disease present and avoid if severe arterial disease.

Note Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

bandage compression 25 cm to 32 cm two layer bandage, 1

13010R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	48.46	7.70	UrgoK2 100397 [UG]

bandage compression 25 cm to 32 cm two layer bandage, 1

13016C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	48.46	7.70	UrgoK2 Lite 100401 [UG]

bandage compression 18 cm to 25 cm two layer bandage, 1

13005L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	42.64	7.70	UrgoK2 100396 [UG]

bandage compression 18 cm to 25 cm two layer bandage, 1

13006M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	42.64	7.70	UrgoK2 Lite 100400 [UG]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

bandage compression four layer bandage, 1

4598B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*205.42	7.70	Profore Lite 66050415 [SN]

bandage compression four layer bandage, 1

4658E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*306.72	7.70	Profore 66050016 [SN]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

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bandage compression 10 cm x 3.5 m high stretch bandage, 1

4657D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*79.07	7.70	Setopress 3505 [MH]

▪ BANDAGE COMPRESSION

Note Use with caution if arterial disease present and avoid if severe arterial disease.

Note Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

Restricted benefit

Venous ulcer

Treatment Phase: Initial treatment

Restricted benefit

Venous ulcer

Treatment Phase: Continuing treatment

bandage compression two layer bandage, 1

4050E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	45.22	7.70	Coban 2 [MM]

▪ BANDAGE RETENTION COHESIVE HEAVY

bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1

4813H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*26.21	7.70	Peg 7423 [MM]

bandage retention cohesive heavy 10 cm x 2 m bandage, 1

4660G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*24.73	7.70	Coban 1584 [MM]

bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1

4814J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*32.39	7.70	Peg 7425 [MM]

bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1

4811F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*20.07	7.70	Peg 7420 [MM]

bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1

4812G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*22.93	7.70	Peg 7422 [MM]

▪ BANDAGE RETENTION COHESIVE LIGHT

bandage retention cohesive light 10 cm x 2 m bandage, 1

4662J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*35.85	7.70	Handygauze Cohesive 8635 [BV]

bandage retention cohesive light 6 cm x 2 m bandage, 1

4719J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*21.99	7.70	Handygauze Cohesive 8633 [BV]

bandage retention cohesive light 2.5 cm x 2 m bandage, 2

4718H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	19.60	7.70	Handygauze Cohesive 8631 [BV]

▪ BANDAGE RETENTION COTTON CREPE

bandage retention cotton crepe 10 cm x 2.3 m bandage, 1

4729X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.95	7.70	Telfa 8254F [KE]
		..	*35.39	7.70	Tensocrepe 36301001 [BV]

bandage retention cotton crepe 5 cm x 2.3 m bandage, 1

4727T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*23.03	7.70	Telfa 8252F [KE]
		..	*25.69	7.70	Tensocrepe 36300501 [BV]

bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1

4728W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*27.21	7.70	Telfa 8253F [KE]
		..	*30.25	7.70	Tensocrepe 36307501 [BV]

▪ BANDAGE TUBULAR

bandage tubular size C (15 cm to 25 cm) straight bandage, 1

4663K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.26	7.70	Elastoplast 2225 [BE]

bandage tubular size D (25 cm to 43 cm) straight bandage, 1

4664L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.26	7.70	Elastoplast 2226 [BE]

bandage tubular size E (35 cm to 45 cm) straight bandage, 1

4665M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.26	7.70	Elastoplast 2227 [BE]

▪ BANDAGE TUBULAR

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bandage tubular 7.5 cm x 1 m bandage, 1

4857P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.90	7.70	Tubigrip D 1546 [MH]

bandage tubular 8.75 cm x 1 m bandage, 1

4858Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.90	7.70	Tubigrip E 1547 [MH]

bandage tubular 10 cm x 1 m bandage, 1

4859R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.90	7.70	Tubigrip F 1548 [MH]

bandage tubular 6.25 cm x 1 m bandage, 1

4855M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.90	7.70	Tubigrip B 1520 [MH]

bandage tubular 6.75 cm x 1 m bandage, 1

4856N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	20.90	7.70	Tubigrip C 1545 [MH]

▪ BANDAGE TUBULAR FINGER

BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1

4798M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	23.33	7.70	Tubegauz 0501633 [SS]

▪ BANDAGE TUBULAR LIGHT WEIGHT

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bandage tubular light weight 10 m large limb size bandage, 1

4673Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	32.34	7.70	Tubifast 2438 [MH]

bandage tubular light weight 10 m medium limb size bandage, 1

4672X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	31.11	7.70	Tubifast 2436 [MH]

bandage tubular light weight 10 m small limb size bandage, 1

4671W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	27.67	7.70	Tubifast 2434 [MH]

▪ BANDAGE TUBULAR LONG STOCKING

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bandage tubular long stocking large size bandage, 1

4799N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*40.17	7.70	Tubigrip 1484 [MH]

bandage tubular long stocking medium size bandage, 1

4797L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*40.17	7.70	Tubigrip 1483 [MH]

bandage tubular long stocking small size bandage, 1

4674B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*40.17	7.70	Tubigrip 1482 [MH]

bandage tubular long stocking XX/large size bandage, 1

4675C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*40.19	7.70	Tubigrip 1486 [MH]

▪ BANDAGE TUBULAR SHORT STOCKING

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage tubular short stocking large D/E size bandage, 1

4816L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.95	7.70	Tubigrip 1481 [MH]

bandage tubular short stocking medium C/D size bandage, 1

4815K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.95	7.70	Tubigrip 1480 [MH]

bandage tubular short stocking small B/C size bandage, 1

4661H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.95	7.70	Tubigrip 1479 [MH]

▪ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

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bandage zinc paste 7.5 cm x 6 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4669R	2	3	..	*33.67	7.70	Steripaste 3610 [MH]

▪ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

bandage zinc paste 7.5 cm x 6 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4750B	2	3	..	*101.89	7.70	Viscopaste 4948 [SN]

bandage zinc paste 80 cm (stockings) bandage, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4760M	‡1	3	..	116.89	7.70	ZipZoc 66000747 [SN]

▪ BETAINE + POLYAMINOPROPYL BIGUANIDE

betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2525X	1	..	..	31.07	7.70	Prontosan Wound Irrigation Solution [BR]

▪ CADEXOMER-IODINE

Note Suitable for yellow sloughy infected and malodorous wounds.

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cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4936T	‡1	2	..	199.73	7.70	Iodosorb 66051340 [SN]

cadexomer-iodine 3 g powder, 7 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4931M	‡1	2	..	91.66	7.70	Iodosorb Powder 66051070 [SN]

cadexomer-iodine 10 cm x 8 cm dressing, 2 x 17 g sheet

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4937W	‡1	..	..	210.48	7.70	Iodosorb 66051360 [SN]

cadexomer-iodine 6 cm x 4 cm dressing, 5 x 5 g sheet

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4935R	‡1	2	..	138.06	7.70	Iodosorb 66051330 [SN]

cadexomer-iodine 50% ointment, 4 x 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4932N	‡1	2	..	146.14	7.70	Iodosorb Ointment 66051240 [SN]

cadexomer-iodine 50% ointment, 2 x 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4933P	‡1	2	..	144.75	7.70	Iodosorb Ointment 66051230 [SN]

▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1

4681J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*99.37	7.70	Actisorb Plus MAP105 [KI]

dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10

4742N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	79.42	7.70	CarboFLEX 403202 [CC]

dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5

4743P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	89.32	7.70	CarboFLEX 403204 [CC]

▪ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate cavity wound 2 g rope, 1

4832H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*106.87	7.70	Sorbsan 1411 [UM]

dressing alginate cavity wound 2 g rope, 5 x 2 g

1905G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*112.41	7.70	Kaltostat 168117 [CC]

▪ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

4682K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*133.79	7.70	Comfeel SeaSorb Filler 3740 [CT]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10

4683L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	90.42	7.70	Kaltostat 168212 [CC]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing alginate superficial wound 10 cm x 10 cm dressing, 10

4700J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	135.11	7.70	Algisite M 66000520 [SN]

dressing alginate superficial wound 15 cm x 20 cm dressing, 10

4691X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	328.97	7.70	Algisite M 66000521 [SN]

dressing alginate superficial wound 5 cm x 5 cm dressing, 10

4699H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	51.94	7.70	Kaltostat 168210 [CC]
		..	71.67	7.70	Algisite M 66000519 [SN]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate superficial wound 10 cm x 10 cm dressing, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4831G	10	1	..	*84.37	7.70	Sorbsan 1410 [UM]
			..	*89.57	7.70	Comfeel SeaSorb Dressing 3710 [CT]

dressing alginate superficial wound 5 cm x 5 cm dressing, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4684M	10	1	..	*49.47	7.70	Comfeel SeaSorb Dressing 3705 [CT]

▪ DRESSING ALGINATE WITH MANUKA HONEY

Note Suitable for yellow sloughy infected and malodorous wounds.

dressing alginate with manuka honey 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10849B	‡1	4	..	71.52	7.70	Algivon Plus CR4225 [DJ]

dressing alginate with manuka honey 2.5 cm x 20 cm ribbon, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10857K	‡1	4	..	83.22	7.70	Algivon Plus Ribbon & Probe CR4231 [DJ]

▪ DRESSING ALGINATE WITH SILVER CAVITY WOUND

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing alginate with silver cavity wound 3 cm x 44 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12765W	‡1	..	..	401.56	7.70	Melgisorb Ag 256605 [MH]

▪ DRESSING ALGINATE WITH SILVER DEEP WOUND

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing alginate with silver deep wound 5 cm x 5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12772F	‡1	..	..	136.82	7.70	Melgisorb Ag 256055 [MH]

dressing alginate with silver deep wound 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12801R	‡1	..	..	237.41	7.70	Melgisorb Ag 256105 [MH]

▪ DRESSING CONTACT LAYER LIPIDOCOLLOID

dressing contact layer lipidocolloid 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13022J	‡1	1	..	71.61	7.70	UrgoTul Contact 100351 [UG]

▪ DRESSING CONTACT LAYER LIPIDOCOLLOID WITH SUCROSE OCTASULFATE

dressing contact layer lipidocolloid with sucrose octasulfate 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13002H	‡1	3	..	125.87	7.70	UrgoStart Contact-Interface-Tul 100380 [UG]

dressing contact layer lipidocolloid with sucrose octasulfate 15 cm x 20 cm dressing, 10

13011T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	229.55	7.70	UrgoStart Contact-Interface-Tul 100381 [UG]

▪ DRESSING FILM

dressing film 15 cm x 20 cm dressing, 1

4688R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	6	..	..	*34.53	7.70	Tegaderm Transparent 1628 [MM]

dressing film 10 cm x 12 cm dressing, 4

4687Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	24.96	7.70	Nexcare Tegaderm Transparent H1626 [MM]

dressing film 6 cm x 7 cm dressing, 8

4686P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	21.48	7.70	Nexcare Tegaderm Transparent H1624 [MM]

▪ DRESSING FILM

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dressing film 10 cm x 12 cm dressing, 10

4893M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	45.71	7.70	Op-Site Flexigrid 4629 [SN]

▪ DRESSING FILM ISLAND

dressing film island 5 cm x 7 cm dressing, 1

4689T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*21.97	7.70	Tegaderm Transparent Island 3582 [MM]

dressing film island 9 cm x 10 cm dressing, 1

4690W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*31.97	7.70	Tegaderm Transparent Island 3586 [MM]

▪ DRESSING FILM ISLAND

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dressing film island 5 cm x 7.2 cm dressing, 5

4898T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*36.95	7.70	Cutifilm Plus 36361370 [SN]

dressing film island 8 cm x 10 cm dressing, 5

4899W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*55.03	7.70	Cutifilm Plus 36361371 [SN]

▪ DRESSING FOAM HEAVY EXUDATE

Restricted benefit

Wounds

Clinical criteria:

- Patient must have a wound with highly viscous exudate.

dressing foam heavy exudate 5 cm x 5 cm dressing, 5

12797M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	38.24	7.70	Mepilex XT 211015 [MH]

dressing foam heavy exudate 10 cm x 10 cm dressing, 5

12760N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	44.26	7.70	Mepilex XT 211100 [MH]

dressing foam heavy exudate 20 cm x 20 cm dressing, 5

12776K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	131.86	7.70	Mepilex XT 211400 [MH]

▪ DRESSING FOAM HEAVY EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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dressing foam heavy exudate 10 cm x 10 cm dressing, 10

4795J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	170.51	7.70	Allevyn 66007637 [SN]

▪ DRESSING FOAM LIPIDOCOLLOID WITH SILICONE HEAVY EXUDATE

dressing foam lipidocolloid with silicone heavy exudate 10 cm x 10 cm dressing, 10

13007N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	94.94	7.70	UrgoTul Absorb Silicone Border 102203 [UG]

▪ DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE

dressing foam lipidocolloid with sucrose octasulfate heavy exudate 8 cm x 8 cm dressing, 10

13023K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	128.96	7.70	UrgoStart Border 100480 [UG]

dressing foam lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10

13017D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	166.53	7.70	UrgoStart Border 100481 [UG]

dressing foam lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 10

13021H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	363.63	7.70	UrgoStart Border 100482 [UG]

▪ DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE

dressing foam lipidocolloid with sucrose octasulfate moderate exudate 10 cm x 10 cm dressing, 10

13008P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	139.08	7.70	UrgoStart Pad 100376 [UG]

dressing foam lipidocolloid with sucrose octasulfate moderate exudate 15 cm x 20 cm dressing, 10

13003J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	301.99	7.70	UrgoStart Pad 100377 [UG]

dressing foam lipidocolloid with sucrose octasulfate moderate exudate 12 cm x 19 cm dressing, 10

13004K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	226.19	7.70	UrgoStart Pad 100378 [UG]

▪ DRESSING FOAM MODERATE EXUDATE

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dressing foam moderate exudate cavity conforming foam, 20 g sachet

4694C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	101.29	7.70	Cavicare 4563 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10

4590N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	169.28	7.70	Allevyn Adhesive 66000044 [SN]

▪ DRESSING FOAM WITH SILICONE

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dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10

10017F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	71.62	7.70	Allevyn Life 66801067 [SN]

dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10

10029W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	100.73	7.70	Allevyn Life 66801068 [SN]

dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10

10023M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	139.06	7.70	Allevyn Life 66801069 [SN]

dressing foam with silicone 21 cm x 21 cm dressing, 10

10021K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	279.64	7.70	Allevyn Life 66801070 [SN]

dressing foam with silicone 10.5 cm x 10.5 cm dressing, 10

11384E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	69.51	7.70	Allevyn Life Non-Bordered 66801748 [SN]

dressing foam with silicone 16 cm x 16 cm dressing, 10

11393P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	118.38	7.70	Allevyn Life Non-Bordered 66801749 [SN]

▪ DRESSING FOAM WITH SILICONE AND SILVER

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

2439J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	106.99	7.70	Mepilex Ag [MH]

dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

2470B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	114.07	7.70	Mepilex Border Ag [MH]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

12206K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	72.49	7.70	Mepilex Border Flex 595311 [MH]

dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10

12184G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	54.43	7.70	Mepilex Border Flex 595211 [MH]

dressing foam with silicone heavy exudate 16 cm x 20 cm dressing, 5

12216Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	85.55	7.70	Mepilex Border Sacrum 282050 [MH]

dressing foam with silicone heavy exudate 22 cm x 25 cm dressing, 5

12207L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	129.26	7.70	Mepilex Border Sacrum 282450 [MH]

dressing foam with silicone heavy exudate 15 cm x 20 cm dressing, 10

12185H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	179.39	7.70	Mepilex Border Flex 595611 [MH]

dressing foam with silicone heavy exudate 22 cm x 23 cm dressing, 6

12195W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	168.99	7.70	Mepilex Border Heel 282750 [MH]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

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dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

4196W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	87.60	7.70	Allevyn Gentle 66800248 [SN]

dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

4230P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	95.01	7.70	Allevyn Gentle Border 66800270 [SN]

dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10

4207K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	67.84	7.70	Allevyn Gentle Border 66800269 [SN]

▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

dressing foam with silicone light exudate 4 cm x 5 cm dressing, 10

12780P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	30.88	7.70	Mepilex Border Lite 281000 [MH]

dressing foam with silicone light exudate 5 cm x 12.5 cm dressing, 5

12774H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	33.46	7.70	Mepilex Border Lite 281100 [MH]

dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5

12804X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	40.45	7.70	Mepilex Border Lite 281300 [MH]

▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

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dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5

4645L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	41.10	7.70	Mepilex Lite 284100 [MH]

dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5

4644K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	32.28	7.70	Mepilex Lite 284000 [MH]

▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

dressing foam with silicone moderate exudate 5 cm x 12.5 cm dressing, 5

12782R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	31.74	7.70	Mepilex Border Flex Lite 581100 [MH]

dressing foam with silicone moderate exudate 4 cm x 5 cm dressing, 10

12777L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	29.05	7.70	Mepilex Border Flex Lite 581011 [MH]

dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

12799P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	38.35	7.70	Mepilex Border Flex Lite 581300 [MH]

▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

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dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

4626L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	45.22	7.70	Mepilex 294100 [MH]

▪ DRESSING FOAM WITH SILVER

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Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing foam with silver 7.5 cm x 7.5 cm dressing, 10

4252T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	174.18	7.70	Allevyn Ag Adhesive 66800073 [SN]

dressing foam with silver 7.5 cm x 7.5 cm dressing, 10

4263J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	174.18	7.70	Allevyn Ag Gentle Border 66800460 [SN]

dressing foam with silver 10 cm x 10 cm dressing, 10

4255Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	258.89	7.70	Allevyn Ag Adhesive 66800075 [SN]

dressing foam with silver 10 cm x 10 cm dressing, 10

4259E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	263.85	7.70	Allevyn Ag Non-Adhesive 66800086 [SN]

dressing foam with silver 10 cm x 10 cm dressing, 10

4266M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	258.89	7.70	Allevyn Ag Gentle Border 66800461 [SN]

dressing foam with silver 12.5 cm x 12.5 cm dressing, 10

4258D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	321.51	7.70	Allevyn Ag Adhesive 66800078 [SN]

dressing foam with silver 12.5 cm x 12.5 cm dressing, 10

4270R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	321.51	7.70	Allevyn Ag Gentle Border 66800462 [SN]

▪ DRESSING GAUZE

dressing gauze eye pad, 12 pads

4768Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	19.05	7.70	Curity 4112 [KE]

▪ DRESSING GAUZE ABSORBENT

dressing gauze absorbent 10 cm x 10 cm pad, 100

4708T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	34.79	7.70	Handy 71117-06 [BV]

dressing gauze absorbent 5 cm x 5 cm pad, 100

4707R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.06	7.70	Handy 71117-05 [BV]

▪ DRESSING GAUZE PARAFFIN

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing gauze paraffin 10 cm x 10 cm dressing, 10

4759L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	30.42	7.70	Jelonet 7404 [SN]

▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

4845B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	38.75	7.70	Bactigras 7457 [SN]

▪ DRESSING GELLING FIBRE

dressing gelling fibre 10 cm x 10 cm dressing, 10

12181D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	76.57	7.70	Exufiber 709901 [MH]

dressing gelling fibre 2 cm x 45 cm dressing, 5

12182E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	53.46	7.70	Exufiber 709909 [MH]

dressing gelling fibre 5 cm x 5 cm dressing, 10

12187K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	42.17	7.70	Exufiber 709900 [MH]

dressing gelling fibre 15 cm x 15 cm dressing, 10

12202F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	159.85	7.70	Exufiber 709903 [MH]

dressing gelling fibre 1 cm x 45 cm dressing, 5

12213T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	53.46	7.70	Exufiber 709908 [MH]

▪ DRESSING GELLING FIBRE

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dressing gelling fibre 10 cm x 10 cm dressing, 10

2486W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	122.70	7.70	Durafiber 66800560 [SN]

dressing gelling fibre 15 cm x 15 cm dressing, 5

2445Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*255.15	7.70	Durafiber 66800561 [SN]

dressing gelling fibre 2 cm x 45 cm rope, 5

2462N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	105.44	7.70	Durafiber 66800563 [SN]

▪ DRESSING GELLING FIBRE LIPIDOCOLLOID

dressing gelling fibre lipidocolloid 15 cm x 20 cm dressing, 10

13009Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	234.25	7.70	UrgoClean Pad 100372 [UG]

dressing gelling fibre lipidocolloid 10 cm x 10 cm dressing, 10

13015B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	106.46	7.70	UrgoClean Pad 100370 [UG]

▪ DRESSING HYDROACTIVE DEBRIDEMENT

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing hydroactive debridement 4 cm dressing, 10

12636C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	93.38	7.70	HydroClean Plus Cavity 609622 [HR]

dressing hydroactive debridement 4 cm dressing, 10

12637D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	89.55	7.70	HydroClean Plus 609602 [HR]

dressing hydroactive debridement 4 cm dressing, 10

4949L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	84.79	7.70	TenderWet 24 Active 609210 [HR]

dressing hydroactive debridement 5.5 cm dressing, 10

12629Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	148.59	7.70	HydroClean Plus 609606 [HR]

dressing hydroactive debridement 5.5 cm dressing, 10

4948K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	86.65	7.70	TenderWet Active Cavity 609272 [HR]

dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10

12660H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	197.64	7.70	HydroClean Plus 609608 [HR]

dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10

4950M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	112.39	7.70	TenderWet 24 Active 609213 [HR]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings

4695D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	108.75	7.70	Tielle MTL101E [KI]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

4696E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	131.99	7.70	Tielle MTL103 [KI]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4929K	‡1	1	..	95.76	7.70	Biatain Adhesive 3420 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4930L	‡1	2	..	92.91	7.70	Biatain Adhesive 3423 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4927H	‡1	1	..	87.56	7.70	Biatain Non-adhesive 3410 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4928J	‡1	2	..	86.21	7.70	Biatain Non-adhesive 3413 [CT]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

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dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4905E	‡1	1	..	81.20	7.70	Allevyn Thin 66047576 [SN]

dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4906F	2	1	..	*145.87	7.70	Allevyn Thin 66047578 [SN]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

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dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4886E	2	1	..	*100.49	7.70	Cutinova Hydro 66047443 [SN]

dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4885D	‡1	1	..	61.94	7.70	Cutinova Hydro 66047441 [SN]

▪ DRESSING HYDROCOLLOID CAVITY WOUND

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid cavity wound paste, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4896Q	10	..	..	*140.87	7.70	DuoDERM Paste 187930 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4907G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	72.82	7.70	DuoDERM Extra Thin 187955 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

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dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4924E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	71.06	7.70	Comfeel Plus Transparent 3533 [CT]

dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10

4888G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	44.26	7.70	Comfeel Plus Transparent 3530 [CT]

dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10

4889H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	84.46	7.70	Comfeel Plus Transparent 3536 [CT]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

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dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4947J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	50.69	7.70	Hydrocoll Thin 900758 [HR]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5

4920Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*216.25	7.70	DuoDERM CGF 187662 [CC]

dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5

4897R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	1	..	*81.63	7.70	DuoDERM CGF 187660 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4921B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	110.32	7.70	Replicare Ultra 66000434 [SN]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4945G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	50.69	7.70	Hydrocoll 900744 [HR]

dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10

4946H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	89.36	7.70	Hydrocoll 900936 [HR]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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dressing hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1

4678F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*57.72	7.70	Comfeel Plus Pressure Relieving 3350 [CT]

DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1

4923D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	82.17	7.70	Comfeel Plus Ulcer Dressing 3110 [CT]

dressing hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1

4679G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*61.82	7.70	Comfeel Plus Pressure Relieving 3353 [CT]

▪ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

10837J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	123.03	7.70	Aquacel Foam Non-Adhesive [CC]

dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

2797F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	99.42	7.70	Aquacel Extra 420672 [CC]

dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5

2803M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*201.95	7.70	Aquacel Extra 420673 [CC]

dressing hydrofibre alternate to alginates 2 cm x 45 cm ribbon, 5

4698G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	83.72	7.70	Aquacel 403770 [CC]

dressing hydrofibre alternate to alginates 12.5 cm x 12.5 cm dressing, 10

10832D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	119.38	7.70	Aquacel Foam Adhesive [CC]

▪ DRESSING HYDROFIBRE WITH SILVER

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing hydrofibre with silver 10 cm x 10 cm dressing, 10

10097K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	257.98	7.70	Aquacel Ag 403708 [CC]

dressing hydrofibre with silver 15 cm x 15 cm dressing, 5

10098L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	275.88	7.70	Aquacel Ag 403710 [CC]

dressing hydrofibre with silver 2 cm x 45 cm ribbon, 5

10105W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	218.48	7.70	Aquacel Ag 403771 [CC]

▪ DRESSING HYDROGEL

dressing hydrogel 7.5 cm x 15 cm dressing, 10

11395R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	115.71	7.70	Sorbact Gel Dressing S98137 [BV]

dressing hydrogel 10 cm x 10 cm dressing, 20

2471C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	186.83	7.70	Sorbact Absorption Dressing S98222 [BV]

dressing hydrogel 10 cm x 10 cm dressing, 5

11709G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	32.01	7.70	Suprasorb G 33631 [LC]

▪ DRESSING HYDROGEL

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dressing hydrogel 12.5 cm x 12.5 cm dressing, 5

12659G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	43.67	7.70	Hydrosorb Comfort 900723 [HR]

▪ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

dressing hydrogel amorphous gel, 50 g

4914P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	3	..	*36.69	7.70	Solugel 10336 [JJ]

dressing hydrogel amorphous gel, 3 x 30 g

4913N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	1	..	*95.91	7.70	DuoDERM Gel H7987 [CC]

▪ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel amorphous gel, 10 x 15 g

4912M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	66.24	7.70	DuoDERM Gel 187990 [CC]
		..	73.16	7.70	Comfeel Purilon Gel 3900 [CT]

▪ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel amorphous gel, 25 g

4894N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	3	..	*86.63	7.70	Intrasite Gel 7313 [SN]

dressing hydrogel amorphous gel, 50 g

4599C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	3	..	*42.45	7.70	SoloSite Gel 36361338 [SN]

▪ DRESSING HYDROGEL FOAM

dressing hydrogel foam 10 cm x 10 cm dressing, 10

2533H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	127.01	7.70	Sorbact Foam Dressing S98310 [BV]

▪ DRESSING HYDROGEL RIBBON

dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

2512F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	189.09	7.70	Sorbact Ribbon Gauze S98118 [BV]

dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

2529D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	186.83	7.70	Sorbact Ribbon Gauze S98120 [BV]

▪ DRESSING HYDROGEL SHEET

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

4911L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*83.27	7.70	Nu-Gel 2497 [KI]

▪ DRESSING HYDROGEL SHEET

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing hydrogel sheet 10 cm x 10 cm dressing, 5

4806Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*55.83	7.70	Hydrosorb 900854 [HR]

▪ DRESSING HYDROPHOBIC

dressing hydrophobic 15 cm x 15 cm foam dressing, 10

11404F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	206.03	7.70	Sorbact Foam Dressing S98315 [BV]

dressing hydrophobic 10 cm x 10 cm dressing, 10

11392N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	200.38	7.70	Sorbact Foam Gentle Border 98532 [BV]

dressing hydrophobic 10 cm x 10 cm dressing, 10

11402D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	91.41	7.70	Sorbact Superabsorbent 98501 [BV]

dressing hydrophobic 15 cm x 15 cm dressing, 10

11394Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	313.28	7.70	Sorbact Foam Gentle Border 98533 [BV]

dressing hydrophobic 20 cm x 20 cm dressing, 10

11403E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	245.54	7.70	Sorbact Superabsorbent 98503 [BV]

▪ DRESSING LIPIDOCOLLOID MODERATE EXUDATE

dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 16

13026N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	121.47	7.70	UrgoTul Lite Border 100357 [UG]

dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 10

13331P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	80.72	7.70	UrgoTul Lite Border 10035710 [UG]

▪ DRESSING NON ADHERENT

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DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1

4243H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	65.46	7.70	Mepitel 290510 [MH]

DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1

4244J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	105.46	7.70	Mepitel 290710 [MH]

▪ DRESSING NON ADHERENT

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing non adherent 7.5 cm x 10 cm dressing, 10

4944F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	21.13	7.70	Atrauman 499513 [HR]

▪ DRESSING NON ADHERENT

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing non adherent 10 cm x 10 cm dressing, 10

4861W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	45.64	7.70	Melolin 66974933 [SN]

dressing non adherent 10 cm x 10 cm dressing, 5

4862X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*33.13	7.70	Cutilin Non-Stick Wound Pad 36361375 [SN]

dressing non adherent 5 cm x 5 cm dressing, 5

4819P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*23.17	7.70	Cutilin Non-Stick Wound Pad 36361374 [SN]

dressing non adherent 5 cm x 5 cm dressing, 5

4860T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*24.85	7.70	Melolin 36361357 [SN]

▪ DRESSING NON-ADHERENT ABSORBENT

dressing non-adherent absorbent 17.5 cm x 22.5 cm hydroactive dressing, 10

12834L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	53.24	7.70	Mextra Superabsorbent 610300 [MH]

dressing non-adherent absorbent 22.5 cm x 32.5 cm hydroactive dressing, 10

12833K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	90.87	7.70	Mextra Superabsorbent 610500 [MH]

dressing non-adherent absorbent 10 cm x 13 cm dressing, 50

12832J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	58.08	7.70	Mesorb 677001 [MH]

dressing non-adherent absorbent 10 cm x 23 cm dressing, 50

12825B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	78.51	7.70	Mesorb 677401 [MH]

dressing non-adherent absorbent 23 cm x 25 cm dressing, 30

12824Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	101.52	7.70	Mesorb 677701 [MH]

dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

11717Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	27.65	7.70	Vliwasorb Pro 32641 [LC]

dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

12837P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	34.21	7.70	Mextra Superabsorbent 610000 [MH]

dressing non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 10

11715N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	38.51	7.70	Vliwasorb Pro 32643 [LC]

dressing non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 10

11718R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	51.09	7.70	Vliwasorb Pro 32644 [LC]

▪ DRESSING NON-ADHERENT ABSORBENT

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing non-adherent absorbent 10 cm x 10 cm hydroactive dressing, 10

12600E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	39.32	7.70	Zetuvit Plus 413710 [HR]

dressing non-adherent absorbent 10 cm x 20 cm hydroactive dressing, 10

12593T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	45.78	7.70	Zetuvit Plus 413711 [HR]

dressing non-adherent absorbent 20 cm x 40 cm hydroactive dressing, 10

12599D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	97.50	7.70	Zetuvit Plus 413715 [HR]

▪ DRESSING NON-ADHERENT WITH SILICONE

dressing non-adherent with silicone 10 cm x 18 cm dressing, 10

12196X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	310.11	7.70	Mepitel One 289500 [MH]

dressing non-adherent with silicone 5 cm x 7.5 cm dressing, 10

12208M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	93.13	7.70	Mepitel One 289100 [MH]

▪ DRESSING NON-ADHERENT WITH SILICONE

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing non-adherent with silicone 7.5 cm x 10 cm dressing, 5

12651W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	66.23	7.70	Atrauman Silicone 499561 [HR]

▪ DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 8 cm x 8 cm dressing, 10

13013X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	205.13	7.70	UrgoStart Plus Border 100460 [UG]

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10

13014Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	266.62	7.70	UrgoStart Plus Non Adhesive 100441 [UG]

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10

13019F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	280.13	7.70	UrgoStart Plus Border 100461 [UG]

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 10

13024L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	637.49	7.70	UrgoStart Plus Border 100462 [UG]

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 5

13018E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	307.27	7.70	UrgoStart Plus Non Adhesive 100442 [UG]

▪ DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate moderate exudate 10 cm x 10 cm dressing, 10

13025M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	210.11	7.70	UrgoStart Plus Pad 100421 [UG]

dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate moderate exudate 15 cm x 20 cm dressing, 10

13012W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	3	..	475.32	7.70	UrgoStart Plus Pad 100422 [UG]

▪ DRESSING TULLE NON-ADHERENT PRIMARY WOUND CONTACT LAYER PARAFFIN

dressing tulle non-adherent primary wound contact layer paraffin 7.6 cm x 7.6 cm dressing, 1

4909J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	1	..	*21.57	7.70	Adaptic 2012 [KI]

▪ DRESSING WITH SILVER

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing with silver 10 cm x 10 cm tulle dressing, 10

12591Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	117.06	7.70	Atrauman Ag 499573 [HR]

dressing with silver 10 cm x 10 cm tulle dressing, 3

4648P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	46.32	7.70	Atrauman Ag 499572 [HR]

▪ DRESSING WITH SILVER

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing with silver 12.5 cm x 12.5 cm hydroactive dressing, 5

4647N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	184.92	7.70	Biatain Ag 9632 [CT]

dressing with silver 10 cm x 10 cm hydroactive dressing, 5

4646M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	170.21	7.70	Biatain Ag 9622 [CT]

▪ GAUZE AND COTTON TISSUE COMBINE ROLL

gauze and cotton tissue combine roll 10 cm x 10 m wrapped pack roll, 1

4761N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	22.84	7.70	JJ 12010 [JJ]

gauze and cotton tissue combine roll 9 cm x 10 m wrapped pack roll, 1

4767X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.23	7.70	BSN 2902165 [BV]

▪ PAD WOUND DEBRIDEMENT

Note If the wound has not healed during this period, further use is to be discontinued after initial pack, no repeats. Where wounds remain unresponsive to standard treatment, patient should be referred on to a specialist.

pad wound debridement pad, 5

11391M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	93.83	7.70	Debrisoft Lolly [LC]

pad wound debridement 10 cm x 10 cm pad, 5

11383D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	93.83	7.70	Debrisoft [LC]

▪ POVIDONE-IODINE

povidone-iodine 9.5 cm x 9.5 cm dressing, 25

10847X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	80.01	7.70	Inadine [KI]

▪ SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE

sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL

11134B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	32.81	7.70	Microdacyn [TF]

▪ TAPE NON WOVEN RETENTION POLYACRYLATE

tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll

4915Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.09	7.70	Medipore 2961 [MM]

▪ TAPE NON WOVEN RETENTION POLYACRYLATE

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tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll

4917T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.61	7.70	Mefix 310250 [MH]

▪ TAPE PLASTER ADHESIVE ELASTIC

tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

4780N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.99	7.70	Leukoplast 01071-00 [BV]

tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

4781P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	25.93	7.70	Leukoplast 01072-00 [BV]

tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

4782Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	29.61	7.70	Leukoplast 01073-00 [BV]

▪ TAPE PLASTER ADHESIVE HYPOALLERGENIC

tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll

4848E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.62	7.70	Nexcare Durable Cloth First Aid Tape 799 [MM]

tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll

4849F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.62	7.70	Nexcare Gentle Paper First Aid Tape 789 [MM]

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4783R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.53	7.70	Leukopor 2471 [BV]

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4785W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.80	7.70	Leukosilk 1021 [BV]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4787Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	20.34	7.70	Leukosilk 1022 [BV]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4794H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.81	7.70	Leukopor 2472 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll

4788B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	22.84	7.70	Leukoflex 1124 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll

4789C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	24.16	7.70	Leukosilk 1024 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll

4790D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	23.33	7.70	Leukopor 2474 [BV]

▪ TAPE PLASTER ADHESIVE WITH SILICONE

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tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll

4239D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	26.46	7.70	Mepitac 298300 [MH]

tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll

4240E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	26.46	7.70	Mepitac 298400 [MH]

Extemporaneously Prepared Benefits

Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
Acacia, powdered	BP	0.03	0.34	3.09	19.62
Acetic Acid (33 per cent)	BP	0.02	0.18	1.75	17.53
Acetic Acid (6 per cent)	BP	0.01	0.04	0.40	4.02
Acetone (use as additive only)	BP	0.02	0.20	1.78	15.85
Alum	BP	0.07	0.70	6.27	55.73
Aluminium Acetate Solution	BP	0.02	0.22	2.01	17.86
Anise Water Concentrated 1 in 40	BP	0.01	0.08	0.80	8.02
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.06	0.51	4.57
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.22	2.22	19.99	126.90
Aspirin	BP	0.38	3.76	33.87	301.08
Belladonna Tincture	BP	0.04	0.36	3.26	28.99
Benzocaine	BP	0.27	2.73	15.62	156.20
Benzoic Acid	BP	0.21	2.13	19.13	121.48
Benzoic Acid Compound Ointment	APF	0.02	0.22	2.01	17.91
Benzoic Acid Solution	BP	0.02	0.23	2.29	22.87
Benzoin Compound Tincture	BP	0.05	0.49	4.43	39.39
Boric Acid (use as additive only)	BP	0.06	0.64	5.76	36.56
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.22	1.99	12.67
Calcium Hydroxide	BP	0.26	2.64	23.75	150.82
Calcium Hydroxide Solution	BP	0.01	0.04	0.36	3.65
Castor Oil (use as additive only)	BP	0.01	0.13	1.16	10.33
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.07	0.61	5.44
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.13	1.17	10.42
Chlorhexidine Acetate (use as additive only)	BP	0.63	6.29	35.96	359.60
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.05	0.49	4.32
Chloroform (use as additive only)	BP	0.11	1.06	9.51	84.57
Chloroform Spirit	BP	0.01	0.10	0.96	9.59
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.13	1.25	12.54
Citric Acid Monohydrate	BP	0.11	1.06	9.55	60.62
Coal Tar	BP	0.06	0.55	4.98	44.27
Coal Tar Solution	BP	0.03	0.27	2.43	15.45
Cocaine Hydrochloride	BP	29.29	292.85	1673.43	16734.34
Coconut Oil	BP	0.06	0.55	4.96	31.50
Codeine Linctus	APF	0.02	0.17	1.53	9.70
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	1.35	13.53	77.30	773.00
Collodion Flexible	BP	0.51	5.11	45.97	291.87
Dithranol	BP	4.17	41.67	238.14	2381.36
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.02	0.16	1.45	12.88
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	2.88	28.79	259.07	1644.88
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.06	0.51	4.53
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.07	0.61	5.45
Ether Solvent (use as additive only)	BP	0.29	2.35	18.83	167.36
Eucalyptus Oil (use as additive only)	BP	0.02	0.20	1.79	15.91

Drug	Standard	Recovery Prices			
		0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
Ferrous Sulfate	BP	0.08	0.83	7.48	47.48
Formaldehyde Solution	BP	0.03	0.33	3.00	26.68
Gentian Alkaline Mixture	APF	0.01	0.09	0.68	6.00
Glycerol	BP	0.01	0.12	1.04	9.21
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.27	2.44
Hydroxybenzoate Compound Solution	APF	0.09	0.68	5.42	48.17
Iodine	BP	1.03	10.32	58.95	589.53
Iodine Alcoholic Solution	BP	0.04	0.40	3.63	23.07
Iodine Aqueous Oral Solution	BP	0.04	0.41	3.71	23.55
Kaolin Mixture	BPC 1968	0.04	0.38	3.45	30.68
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.82	7.27
Lactic Acid	BP	0.34	3.36	30.21	191.81
Lavender Spike Oil	BPC 1968	0.13	1.29	11.57	73.44
Liquorice Liquid Extract	BP	0.19	1.85	16.69	148.34
Magnesium Carbonate Light	BP	0.05	0.37	2.92	25.99
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.03	0.28	2.48
Magnesium Trisilicate	BP	0.06	0.59	5.27	46.82
Menthol, Racemic or Levomenthol	BP	0.28	2.81	25.28	160.48
Methyl Hydroxybenzoate	BP	0.47	4.73	42.60	270.48
Methyl Hydroxybenzoate Solution	APF	0.05	0.48	4.76	47.62
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.01	0.12	1.07
Olive Oil (use as additive only)	BP	0.01	0.10	0.89	7.92
Paraffin Hard	BP	0.07	0.71	6.40	56.85
Paraffin Light Liquid	BP	0.01	0.14	1.25	7.96
Paraffin Liquid (use as additive only)	BP	0.01	0.10	0.88	7.82
Paraffin Soft White	BP	0.01	0.08	0.68	6.03
Peppermint Oil (use as additive only)	BP	0.10	1.00	9.03	57.32
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.05	0.46	4.10	36.48
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	1.39	13.94	125.45	796.48
Phenol Liquefied (not available for ear drops)	BP	0.05	0.55	4.93	31.32
Podophyllum Resin	BP	4.63	46.31	264.64	2646.40
Potassium Citrate	BP	0.03	0.33	2.96	26.29
Potassium Iodide	BP	0.55	5.51	49.55	314.62
Potassium Permanganate	BP	0.04	0.43	3.83	34.07
Propyl Hydroxybenzoate	BP	0.44	4.38	39.45	250.48
Propylene Glycol	BP	0.03	0.28	2.52	16.01
Resorcinol	BP	0.45	3.57	28.59	254.15
Salicylic Acid	BP	0.05	0.47	4.26	27.08
Salicylic Acid Ointment	APF	0.02	0.16	1.45	12.91
Salicylic Acid Ointment	BP	0.02	0.16	1.45	12.91
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.16	1.48	13.19
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Sodium Bicarbonate	BP	0.04	0.36	3.22	28.58
Sodium Chloride	BP	0.03	0.29	2.58	22.89
Sodium Chloride Solution	BP	0.01	0.01	0.13	1.27
Sodium Citrate	BP	0.15	1.55	13.91	88.29
Sodium Thiosulfate (use as additive only)	BP	0.09	0.88	7.89	70.16
Starch	BP	0.02	0.22	1.94	17.23
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.01	0.15	1.45	14.52
Sulfur Precipitated	BP 1980	0.03	0.29	2.65	16.83
Syrup	BP	0.01	0.06	0.57	5.09
Talc Purified, sterilised	BP	5.54	55.37	498.35	4429.78
Thymol	BP	0.56	5.64	50.79	322.48
Thymol Compound Mouth Wash	APF 15	0.01	0.10	0.94	8.37
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.58	40.73
Tragacanth Mucilage	APF 13	0.01	0.11	1.07	10.72
Tragacanth Mucilage	BPC 1973	0.01	0.10	1.00	10.01
Tragacanth, powdered	BP	0.70	7.03	63.28	401.77
Trichloroacetic Acid	BP 1980	0.32	3.25	29.23	185.56

Drug	Standard	Recovery Prices			
		0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
Triethanolamine	BP	0.17	1.69	15.17	96.29
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0.00	0.00	0.00	5.61
Water Purified	BP	0.01	0.01	0.11	1.02
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.03	0.21	1.64	14.55
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.48	13.18
Wool Fat	BP	0.03	0.33	2.93	26.05
Wool Fat Hydrous	BP	0.03	0.30	2.66	23.67
Zinc Compound Paste	BP	0.04	0.45	4.03	35.81
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.03	0.32	2.88	25.60
Zinc Oxide	BP	0.03	0.34	3.05	27.10
Zinc Sulfate	BP	0.08	0.83	7.49	47.55
Zinc and Salicylic Acid Paste	BP	0.04	0.37	3.36	29.86

Container Prices

Type	Container	Price $
Dispensing Bottles	25mL	1.74
Dispensing Bottles	50mL	0.73
Dispensing Bottles	100mL	0.85
Dispensing Bottles	200mL	0.87
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	0.92
Poison Bottles	50mL	1.23
Poison Bottles	100mL	1.28
Poison Bottles	200mL	1.35
Poison Bottles	500mL	2.00
Poison Bottles	600mL	4.05
Poison Bottles	1000mL	3.99
Dropper Containers (Glass)	15mL	1.68
Dropper Containers (Polythene)	15mL	0.98
Screw Cap Jars	25g	1.07
Screw Cap Jars	50g	1.36
Screw Cap Jars	100g	1.37
Screw Cap Jars	200g	0.77
Screw Cap Jars	500g	2.19
Screw Cap Jars	1000g	4.39

Standard Formula Preparations

Code	Item	Reference	DPMQ $	MRVSN $
	Creams			
	(Maximum Quantity 100 g and 1 Repeat)			
7502W	Salicylic Acid and Sulfur Aqueous	APF	18.08	19.95
	Ear Drops			
	(Maximum Quantity 15 ml and 2 Repeats)			
7643G	Aluminium Acetate	BP	14.72	16.59
7642F	Aluminium Acetate	APF	13.59	15.46
7314Y	Sodium Bicarbonate	APF & BP	12.59	14.46
7313X	Spirit	APF	12.16	14.03
	Inhalations			
	(Maximum Quantity 50 ml and 1 Repeat)			
7484X	Benzoin and Menthol	APF	36.54	31.60
7308P	Menthol	APF	17.27	19.14
7310R	Menthol and Eucalyptus	BP1980	17.91	19.78
	Linctuses containing Codeine Phosphate			
	(Maximum Quantity 100 ml and 0 Repeat)			
7530H	Codeine	APF	21.43	23.30
	Lotions			
	(Maximum Quantity 200 ml and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	16.03	17.90
	Mixtures, Other			
	(Maximum Quantity 200 ml and 4 Repeats)			
7348R	Kaolin	BPC 1968	55.57	31.60
7342K	Magnesium Trisilicate	BPC 1968	28.41	30.28
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	30.07	31.60
	Ointments, Waxes			
	(Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF & BP	30.10	31.60
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	24.91	26.78
7926E	Salicylic Acid	APF	25.10	26.97
7928G	Salicylic Acid (extemporaneous formula)	BP	25.10	26.97
	Paints			
	(Maximum Quantity 25 ml and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	194.86	31.60
7568H	Salicylic Acid	APF	116.32	31.60
	Pastes, Other			
	(Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF & BP	47.95	31.60
	Powders for Internal Use			
	(Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	58.36	31.60

Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 ml	2
19B	Eye Drops containing Cocaine Hydrochloride	15 ml	..
22E	Eye Drops, Other	15 ml	5
23F	Eye Lotions	200 ml	2
29M	Inhalations	50 ml	1
64J	Linctuses containing Codeine Phosphate	100 ml	..
34T	Linctuses, Other	100 ml	2
39C	Lotions	200 ml	2
65K	Mixtures containing Codeine Phosphate	200 ml	..
66L	Mixtures for Children containing Codeine Phosphate	100 ml	..
41E	Mixtures for Children, Other	100 ml	4
40D	Mixtures, Other	200 ml	4
30N	Mouth Washes	200 ml	1
42F	Nasal Instillations	15 ml	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 ml	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 ml	2

Index of Manufacturers' Code

Code	Manufacturer
AB	Abbott Australasia Pty Ltd
AE	AFT Pharmaceuticals (AU) Pty Ltd
AF	Alphapharm Pty Ltd
AL	Alphapharm Pty Ltd
AN	Amgen Australia Pty Limited
AP	AstraZeneca Pty Ltd
AQ	Alcon Laboratories (Australia) Pty Ltd
AS	Aspen Pharmacare Australia Pty Limited
AV	sanofi-aventis Australia Pty Ltd
BB	Blackmores Limited
BD	Biogen Australia Pty Ltd
BE	Beiersdorf Australia Ltd
BG	Sandoz Pty Ltd
BN	Bayer Australia Ltd
BQ	Bristol-Myers Squibb Australia Pty Ltd
BR	B. Braun Australia Pty Ltd
BV	BSN medical (Aust.) Pty Ltd
BX	Baxter Healthcare Pty Limited
BY	Boehringer Ingelheim Pty Ltd
BZ	Boucher & Muir Pty Ltd
CC	ConvaTec Australia Pty Ltd
CF	CNS Pharma Pty Ltd
CJ	Celgene Pty Limited
CR	Pharmacor Pty Limited
CS	Seqirus (Australia) Pty Ltd
CT	Coloplast Pty Ltd
CU	Care Pharmaceuticals Pty Limited
CX	Contact Lens Centre Australia Limited
DE	Stallergenes Australia Pty Ltd
DJ	De Fries Industries Pty Ltd
DQ	Church & Dwight (Australia) Pty Ltd
DV	Medical Developments International Limited
DX	Ascensia Diabetes Care Australia Pty Limited
DZ	Medsurge Healthcare Pty Ltd
EI	Eisai Australia Pty Ltd
EJ	Encapsulate Pharma Pty Ltd
EO	Ego Pharmaceuticals Pty Ltd
EU	Chiesi Australia Pty Ltd
EV	Teva Pharma Australia Pty Ltd
EW	Celltrion Healthcare Australia Pty Ltd
FB	Pierre Fabre Australia Pty Ltd
FD	Dr Falk Pharma Australia Pty Ltd
FF	Phebra Pty Ltd
FG	Phebra Pty Ltd
FI	Boehringer Ingelheim Pty Ltd
FJ	Pharmaco (Australia) Limited
FK	A.Menarini Australia Pty Limited
FP	Ferring Pharmaceuticals Pty Limited
FQ	Pharmaco (Australia) Limited
FX	Gedeon Richter Australia Pty Ltd
FZ	Pfizer Australia Pty Ltd
GA	Galderma Australia Pty Ltd
GC	GlaxoSmithKline Australia Pty Ltd
GG	Gem Pharma Pty Ltd
GH	Amdipharm Mercury (Australia) Pty Limited
GI	Gilead Sciences Pty Limited
GJ	HALEON AUSTRALIA PTY LTD
GK	GlaxoSmithKline Australia Pty Ltd
GN	Actavis Pty Ltd
GO	Viatris Pty Ltd
GQ	Generic Health Pty Ltd
GT	Viatris Pty Ltd
GX	Apotex Pty Ltd
GZ	sanofi-aventis Australia Pty Ltd
HB	Besins Healthcare Australia Pty Ltd
HQ	Generic Health Pty Ltd
HR	Paul Hartmann Pty Ltd
HT	BTC Speciality Health Pty Ltd
HW	HAMELN PHARMA PTY. LTD.
HX	Sandoz Pty Ltd
IB	Apotex Pty Ltd
IE	BeiGene AUS Pty Ltd
IG	Sigma Company Limited
IL	iNova Pharmaceuticals (Australia) Pty Limited
IM	iNova Pharmaceuticals (Australia) Pty Limited
IO	BioMarin Pharmaceutical Australia Pty Ltd
IQ	Alcon Laboratories (Australia) Pty Ltd
IR	Indivior Pty Ltd
IS	Ipsen Pty Ltd
IT	InterPharma Pty Ltd
IU	AU Pharma Pty Ltd
IX	Clinect Pty Ltd
IY	Clinect Pty Ltd
JA	JAZZ PHARMACEUTICALS ANZ PTY LTD
JB	Apotex Pty Ltd
JC	Janssen-Cilag Pty Ltd
JJ	Johnson & Johnson Medical Pty Ltd
JM	Glenmark Pharmaceuticals (Australia) Pty Ltd
JO	Juno Pharmaceuticals Pty Ltd
JT	Johnson & Johnson Pacific Pty Limited
JU	Juno Pharmaceuticals Pty Ltd
JX	Juno Pharmaceuticals Pty Ltd
JZ	Juniper Biologics Pty Ltd
KE	Kendall Australasia Pty Ltd
KI	KCI Medical Australia Pty Ltd
KO	KYOWA KIRIN AUSTRALIA PTY LTD
KP	Eli Lilly Australia Pty Ltd
KY	Key Pharmaceuticals Pty Ltd
LC	Lohmann & Rauscher Pty Ltd
LL	Astellas Pharma Australia Pty Ltd
LM	Link Medical Products Pty Ltd
LN	Aspen Pharmacare Australia Pty Limited
LO	Leo Pharma Pty Ltd
LQ	Astellas Pharma Australia Pty Ltd
LR	Cipla Australia Pty Ltd
LS	Astellas Pharma Australia Pty Ltd
LT	Aspen Pharmacare Australia Pty Limited
LU	Lundbeck Australia Pty Ltd
LX	Lawley Pharmaceuticals Pty Ltd
LY	Eli Lilly Australia Pty Ltd
MF	Mundipharma Pty Limited
MH	Molnlycke Health Care Pty Ltd
MK	Merck Sharp & Dohme (Australia) Pty Ltd
MM	3M Pharmaceuticals Australia Pty Ltd
MQ	Alphapharm Pty Ltd
MT	Mentholatum Australasia Pty Ltd
MW	Biomed Aust Pty Limited
NB	Nova Pharmaceuticals Australasia Pty Ltd
NE	Norgine Pty. Ltd.
NF	Novo Nordisk Pharmaceuticals Pty. Limited
NI	Novo Nordisk Pharmaceuticals Pty. Limited
NM	Novartis Pharmaceuticals Australia Pty Limited
NO	Novo Nordisk Pharmaceuticals Pty. Limited
NP	Nice-Pak Products Pty. Ltd
NQ	Takeda Pharmaceuticals Australia Pty. Ltd.
NT	Nestle Australia Ltd
NU	Nutricia Australia Pty Limited
NV	Novartis Pharmaceuticals Australia Pty Limited
OB	Oral B Laboratories Pty Ltd
OC	Accord Healthcare Pty. Ltd.
OH	Orpharma Pty Ltd
OJ	The Trustee for ORSPEC PHARMA UNIT TRUST
OM	Colgate Oral Care
ON	Orion Laboratories Pty. Ltd.
OQ	Organon Pharma Pty Ltd
OS	Otsuka Australia Pharmaceutical Pty. Ltd
OU	Oraderm Pharmaceuticals Pty Ltd
OV	Organon Pharma Pty Ltd

Code	Manufacturer
OW	Arrow Pharma Pty Ltd
OX	Orion Pharma (Aus) Pty Limited
PB	Pharmaco (Australia) Limited
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
PP	Petrus Pharmaceuticals Pty Ltd
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd
QH	Cortex Health Pty Ltd
QS	Sandoz Pty Ltd
QY	Pro Pharmaceuticals Group Pty. Ltd.
RA	Sun Pharma ANZ Pty Ltd
RB	Bio Revive Pty Ltd
RC	Reckitt Benckiser (Australia) Pty Limited
RF	Arrow Pharma Pty Ltd
RI	Dr Reddy's Laboratories (Australia) Pty Ltd
RJ	Recordati Rare Diseases Australia Pty. Ltd.
RM	Pharmacor Pty Limited
RN	Sun Pharma ANZ Pty Ltd
RO	Roche Products Pty Ltd
RQ	Reach Pharmaceuticals Pty Ltd
RW	Arrow Pharma Pty Ltd
RX	Servier Laboratories (Aust.) Pty. Ltd.
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SA	SciGen (Australia) Pty Limited
SB	Nutricia Australia Pty Limited
SE	Servier Laboratories (Aust.) Pty. Ltd.
SG	Merck Healthcare Pty Ltd
SI	Sigma Company Limited
SN	Smith & Nephew Pty Limited
SS	SSL Australia Pty Ltd
SW	sanofi-aventis Australia Pty Ltd
SY	Bayer Australia Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Ltd
TD	STADA Pharmaceuticals Australia Pty Limited
TF	Te Arai BioFarma Limited
TG	ANTENGENE (AUS) PTY. LTD.
TK	Takeda Pharmaceuticals Australia Pty. Ltd.
TN	Medtas Pty Ltd
TQ	Terumo BCT Australia Pty Limited
TT	Theramex Australia Pty Ltd
TW	Apotex Pty Ltd
TX	Apotex Pty Ltd
TY	Apotex Pty Ltd
UC	UCB Australia Proprietary Limited
UG	Urgo Medical Australia Pty Ltd
UJ	Upjohn Australia Pty Ltd
UL	Bausch & Lomb (Australia) Pty Ltd
UM	Unomedical Pty Ltd
UN	Unilever Australia Limited
UO	Bausch & Lomb (Australia) Pty Ltd
UR	Camurus Pty Ltd
VB	AbbVie Pty Ltd
VE	AbbVie Pty Ltd
VF	Vitaflo Australia Pty Limited
VI	ViiV Healthcare Pty Ltd
VL	Vifor Pharma Pty Limited
VO	Avallon Pharmaceuticals Pty Limited
VR	Vertex Pharmaceuticals (Australia) Pty. Ltd.
VZ	Sanofi-aventis Healthcare Pty Ltd
WA	sanofi-aventis Australia Pty Ltd
WZ	Bridgewest Perth Pharma Pty Ltd
XC	Southern Cross Pharma Pty Ltd
XH	MS Health Pty Ltd
XI	Alexion Pharmaceuticals Australasia Pty Ltd
XN	Southern XP Pty Ltd
XO	Echo Therapeutics Pty Ltd
XT	Arrotex Pharmaceuticals Pty Ltd
XW	Arrotex Pharmaceuticals Pty Ltd
XY	MAXX PHARMA PTY LTD
YG	EUGIA PHARMA (AUSTRALIA) PTY LTD
YN	Mayne Pharma International Pty Ltd
YO	The Trustee for ORSPEC PHARMA UNIT TRUST
YT	Mayne Products Pty Ltd
ZB	Specialised Therapeutics Pm Pty Ltd
ZE	Seekwell Pty Ltd
ZO	Swedish Orphan Biovitrum Pty Ltd
ZP	Medis Pharma Pty Ltd
ZS	Strides Pharma Science Pty Ltd

Generic/Proprietary Index

ABATACEPT 467, 469, 472
ABEMACICLIB..... 390, 391
Abilify Maintena(LU) *1474*
Abilify(OS)..... *1473*
ABIRATERONE 464
ABIRATERONE (&) METHYLPREDNISOLONE
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS..... 464, 465
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS 260, 261
Abisart 150(AL)..... *171*, *172*
Abisart 300(AL)..... *171*, *172*
Abisart 75(AL)..... *171*, *172*
Abisart HCTZ 150/12.5(AL) *175*, *176*
Abisart HCTZ 300/12.5(AL) *176*
Abisart HCTZ 300/25(AL) *176*
Abstral(FK)..... *1633*, *1634*
Abyraz (AF)..... *1473*
ACALABRUTINIB 403, 404
ACAMPROSATE 1511
Acamprosate Mylan(AL) *1511*
ACAMPROSATE VIATRIS (MQ) *1511*
ACARBOSE..... 88
Acarbose Mylan(AF) *88*
Acarbose Viatris (AL)..... *88*
Acarbose Viatris(AL)..... *88*
Accomin Adult Tonic(PF) *1656*
Accupril(PF) *161*
Accuretic 10/12.5mg(PF) *166*
Accuretic 20/12.5mg(PF) *166*
ACETAZOLAMIDE 1547
Acetec(AL) *158*
ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID..... 1665
ACICLOVIR
.ANTIINFECTIVES FOR SYSTEMIC USE..... 302, 303
.SENSORY ORGANS 1541
Aciclovir APOTEX(TY)..... *303*
Aciclovir GH (GQ) *303*
Aciclovir Sandoz (HX)..... *303*
Aciclovir Sandoz(HX)..... *303*
Aci-Jel(CU) *1665*
Acimax Tablets(FJ)..... *43*, *44*, *45*
ACITRETIN..... 221
Aclasta(HX)..... *1366*
ACLIDINIUM 1535
ACLIDINIUM + FORMOTEROL..... 1529
Aclor 125(MQ) *284*
Aclor 250(MQ) *284*, *285*
Acpio 15(RF)..... *88*, *89*
Acpio 30(RF)..... *88*, *89*
Acpio 45(RF)..... *88*, *89*
ACQUIN(RF)..... *161*
Actaze (RW) *88*, *89*
Actemra ACTPen(RO).....*1151*, *1153*, *1154*, *1156*, *1158*, *1159*, *1160*, *1162*, *1164*, *1165*, *1166*, *1169*, *1173*, *1177*, *1180*, *1182*, *1187*
Actemra Subcutaneous Injection(RO) *1151*, *1153*, *1154*, *1156*, *1158*, *1159*, *1160*, *1162*, *1164*, *1165*, *1166*, *1169*, *1173*, *1177*, *1180*, *1183*, *1187*
Actiq(TB)..... *1633*, *1634*
Actisorb Plus MAP105(KI) *1683*
Actonel EC(TT)..... *1365*, *1671*
Actonel Once-a-Month(TT) *1364*, *1365*
Actonel(TT).....*1364*, *1365*, *1366*, *1671*, *1672*
Actos(EW)..... *88*, *89*
Actrapid Penfill 3 mL(NO) *72*
Actrapid(NO)..... *72*
Adalicip(LR)... *481*, *482*, *487*, *489*, *490*, *492*, *494*, *495*, *498*, *500*, *502*, *504*, *506*, *508*, *509*, *511*, *512*, *516*, *520*, *522*, *525*, *527*, *535*, *537*, *539*, *540*, *544*, *547*, *549*, *551*, *553*, *564*, *567*, *573*, *576*, *579*, *582*, *585*, *588*, *590*, *593*, *603*, *606*, *616*, *621*, *626*, *632*, *636*, *641*, *651*, *656*, *660*, *668*, *681*, *684*, *699*, *716*, *720*, *724*, *729*, *734*, *738*, *780*, *781*, *786*, *799*, *806*
ADALIMUMAB..... 479, 481, 482, 483, 484, 487, 489, 490, 492, 494, 496, 498, 500, 502, 504, 506, 508, 509, 511, 512, 514, 516, 518, 520, 522, 525, 527, 529, 533, 535, 537, 539, 541, 544, 547, 549, 551, 553, 555, 558, 561, 564, 567, 571, 573, 576, 579, 582, 585, 588, 590, 593, 596, 600, 603, 606, 611, 613, 616, 621, 626, 629, 632, 636, 641, 647, 651, 656, 660, 664, 668, 672, 675, 678, 681, 684, 689, 694, 696, 699, 702, 707, 711, 716, 720, 724, 729, 734, 738, 742, 747, 751, 756, 760, 764, 770, 775, 781, 786, 792, 799, 806, 813
ADAPALENE + BENZOYL PEROXIDE.....231, 232
Adaptic 2012(KI).....*1699*
Addos XR 30(RW).....*156*, *157*
Addos XR 60(RW).....*156*, *157*
Adenuric(FK) *1361*
Adesan HCT 16/12.5(AF) *174*, *175*
Adesan HCT 32/12.5(AF) *174*, *175*
Adesan HCT 32/25(AF).....*174*, *175*
Adesan(AF) *169*, *170*
ADRENALINE (EPINEPHRINE)
.CARDIOVASCULAR SYSTEM.....131, 132
.Prescriber Bag 26
.RESPIRATORY SYSTEM 1537, 1538
Adrenaline Jr Viatris(AF)
.CARDIOVASCULAR SYSTEM.....*132*
.RESPIRATORY SYSTEM *1538*
Adrenaline Viatris(AF)
.CARDIOVASCULAR SYSTEM.....*132*
.RESPIRATORY SYSTEM *1538*
ADT Booster(CS).....*26*, *313*
ADVAGRAF XL(LQ) *1231*, *1232*
Advantan (Fatty)(LO).....*226*, *227*, *228*
Advantan(LO) *226*, *227*, *228*
Aeron 250(AL) *1536*
Aeron 500(AL) *1536*
AFATINIB 375, 376
Afinitor(NV).....*395*, *396*, *397*, *398*
AFLIBERCEPT.....1552, 1553, 1554, 1555, 1556, 1557
Aggrastat(AS).....*114*
Airomir Autohaler(IL) *1518*
Ajovy(TB).....*1430*
Akamin 50(AF) *274*
AKM Fingolimod(RW).....*1233*
Akynzeo IV(JZ).....*51*
Akynzeo(JZ) *52*
ALBENDAZOLE 1515
Albey Bee Venom(DE) *1575*
Albey Paper Wasp Venom(DE) *1575*
Albey Yellow Jacket Venom(DE).....*1576*
Aldactone(PF) *147*
Aldara Pump(IL) *236*, *1664*
Aldara(IL).....*236*, *1664*
Aldiq(AF) *236*, *1664*
Aldomet(AS).....*140*
Alecensa(RO).....*384*
ALECTINIB.....384
ALENDRONATE 1362, 1363
ALENDRONATE + COLECALCIFEROL ..1367, 1368, 1672
Alendronate Sandoz(SZ).....*1362*, *1363*
Alepam 15(AF) *1483*, *1484*, *1643*
Alepam 30(AF) *1483*, *1484*, *1643*
Alfamino Junior(NT).....*1598*, *1599*

Alfamino(NT) *1591*, *1593*
Alfaré(NT) *1596*
ALFUZOSIN 1667
Algisite M 66000519(SN) *1683*
Algisite M 66000520(SN) *1683*
Algisite M 66000521(SN) *1683*
Algivon Plus CR4225(DJ) *1684*
Algivon Plus Ribbon & Probe CR4231(DJ) *1684*
ALIROCUMAB 192, 193
Alkeran(AS) *313*
Allegron(RW) *1488*
Allereze(AF) *1676*
Allevyn 66007637(SN) *1686*
Allevyn Adhesive 66000044(SN) *1687*
Allevyn Ag Adhesive 66800073(SN) *1689*
Allevyn Ag Adhesive 66800075(SN) *1689*
Allevyn Ag Adhesive 66800078(SN) *1689*
Allevyn Ag Gentle Border 66800460(SN) *1689*
Allevyn Ag Gentle Border 66800461(SN) *1689*
Allevyn Ag Gentle Border 66800462(SN) *1689*
Allevyn Ag Non-Adhesive 66800086(SN) *1689*
Allevyn Gentle 66800248(SN) *1688*
Allevyn Gentle Border 66800269(SN) *1688*
Allevyn Gentle Border 66800270(SN) *1688*
Allevyn Life 66801067(SN) *1687*
Allevyn Life 66801068(SN) *1687*
Allevyn Life 66801069(SN) *1687*
Allevyn Life 66801070(SN) *1687*
Allevyn Life Non-Bordered 66801748(SN) *1687*
Allevyn Life Non-Bordered 66801749(SN) *1687*
Allevyn Thin 66047576(SN) *1692*
Allevyn Thin 66047578(SN) *1692*
Allmercap(LM) *315*
ALLOPURINOL 1360, 1361
Allopurinol APOTEX(GX) *1360*, *1361*
Allopurinol Sandoz (SZ) *1360*, *1361*
Allosig(RF) *1360*, *1361*
Alodorm(AF)
.Palliative Care *1643*
Alodorm(AF)
.NERVOUS SYSTEM *1434*, *1484*
ALOGLIPTIN 89
ALOGLIPTIN + METFORMIN 77
Aloxi(JZ) *54*
Alpha Keri Bath Oil(MT) *1661*
Alpha Keri Lotion(MT) *1661*
Alphaclav Duo Forte Viatris (AL) *280*, *281*
AlphaClav Duo Forte(AF) *280*, *281*
AlphaClav Duo(AF) *280*, *281*
Alphagan P 1.5(VE) *1546*
Alphagan(VE) *1546*
Alphamox 250(AF) *274*, *275*, *276*
Alphamox 500(AF) *274*, *275*, *276*
Alprax 0.5(AS) *1482*
Alprax 1(AS) *1482*
ALPRAZOLAM 1482
Alprim(AF) *287*
ALPROSTADIL 1665
Alunbrig(TK) *385*
Alvesco 160(EU) *1534*
Alvesco 80(EU) *1534*
Alzene(AF) *1676*
Alziras(RW) *1464*
AMANTADINE 1460
AMANTAMED(DZ) *1460*
Amaryl(SW) *76*
Amcal Mag-A(IG) *1657*
AMCLAVOX DUO 500/125 (RW) *280*, *281*
AMCLAVOX DUO FORTE 875/125(RW) *280*, *281*
Amdarone(XT) *131*
Amdipharm Mercury (Australia) Pty Limited(GH)
.CARDIOVASCULAR SYSTEM *149*
.GENITO URINARY SYSTEM AND SEX HORMONES *255*
Amgevita(XT) *481*, *482*, *484*, *486*, *489*, *490*, *492*, *494*, *495*, *498*, *500*, *502*, *504*, *506*, *507*, *509*, *511*, *512*, *514*, *516*, *520*, *522*, *524*, *527*, *529*, *535*, *537*, *538*, *540*, *544*, *547*, *549*, *551*, *553*, *564*, *567*, *570*, *573*, *576*, *579*, *582*, *585*, *588*, *590*, *593*, *596*, *600*, *613*, *621*, *626*, *629*, *664*, *672*, *675*, *678*, *689*, *693*, *696*, *702*, *707*, *711*, *742*, *747*, *751*, *756*, *760*, *764*, *770*, *775*, *791*, *813*, *820*
AMIFAMPRIDINE 1511
AMILORIDE + HYDROCHLOROTHIAZIDE 147
AMILOXYN (RF) *274*, *275*, *276*
AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS 1600, 1601
AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE 1602
AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE 1603
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID 1604
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS, WITHOUT PHENYLALANINE AND TYROSINE 1604
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES
.VARIOUS 1597, 1598, 1604, 1605
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN 1606, 1607
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE 1607
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE 1607, 1608
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE 1608, 1609
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE 1609
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE 1609, 1610
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID 1610

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID 1610
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID 1611
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID 1611
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID 1611
AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE 1611
AMINO ACID FORMULA WITHOUT PHENYLALANINE 1611
AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE 1612
AMINO ACID SYNTHETIC FORMULA 1583, 1584
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS 1585, 1586
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES ... 1588, 1589, 1590, 1591
AMIODARONE 131
Amiodarone Sandoz (SZ) *131*
Amipride 400(RW) *1473*
Amira 150(AF) *1492*
Amira 300(AF) *1492*
AMISULPRIDE 1473
Amisulpride Sandoz Pharma (HX) *1473*
Amisulpride Sandoz Pharma(HX) *1473*
AMITRIPTYLINE 1486
Amitriptyline Lupin(GQ) *1486*
Amitriptyline Viatris 10 (AL) *1486*
Amitriptyline Viatris 25 (AL) *1486*
Amitriptyline Viatris 50 (AL) *1486*
Amlo 10(RW) *155*
Amlo 5(RW) *155*
AMLODIPINE 155
AMLODIPINE + ATORVASTATIN 218
AMLODIPINE + VALSARTAN 179, 180
AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE 183
Amlodipine APOTEX (GX) *155*
Amlodipine GH(GQ) *155*
Amlodipine Sandoz (SZ) *155*
Amlodipine/Valsartan Novartis 10/160(NM) *180*
Amlodipine/Valsartan Novartis 10/320(NM) *180*
Amlodipine/Valsartan Novartis 5/160(NM) *180*
Amlodipine/Valsartan Novartis 5/320(NM) *180*
Amlodipine/Valsartan Novartis 5/80(NM) *180*
Amlodipine/Valsartan/HCT Novartis 10/160/12.5(NM) ... *183*
Amlodipine/Valsartan/HCT Novartis 10/160/25(NM) *183*
Amlodipine/Valsartan/HCT Novartis 10/320/25(NM) *183*
Amlodipine/Valsartan/HCT Novartis 5/160/12.5(NM) *183*
Amlodipine/Valsartan/HCT Novartis 5/160/25(NM) *183*, *184*
AMOROLFINE 1659
AMOXICILLIN 274, 275
AMOXICILLIN + CLAVULANIC ACID 280, 281
Amoxil Forte(AS) *274*
Amoxil(AS) *274*, *275*, *276*
Amoxycillin generichealth 500(GQ) *274*, *275*, *276*
Amoxycillin Sandoz (SZ) *274*, *275*, *276*
Amoxycillin Sandoz(BG) *275*
Amoxycillin Sandoz(SZ) *274*
Amoxycillin/Clavulanic Acid 500/125 APOTEX(TY) *280*, *281*
AmoxyClav generichealth 875/125 (HQ) *280*, *281*
AMPHOTERICIN B 36
Anafranil 25(PB) *1487*
Anapen 300 (XT) *132*, *1538*
Anapen 500(XT)
.CARDIOVASCULAR SYSTEM *132*
.RESPIRATORY SYSTEM *1538*
Anapen Junior 150 (XT) *132*, *1538*
Anaprox 550(IX) *1358*, *1624*
ANASTROZOLE 462
Anastrozole GH(GQ) *462*
Anastrozole Sandoz (SZ) *462*
Androcur(GH)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *459*
.GENITO URINARY SYSTEM AND SEX HORMONES *253*
Androcur-100(GH)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *459*
.GENITO URINARY SYSTEM AND SEX HORMONES *253*
AndroForte 5(LX) *242*
Anoro Ellipta 62.5/25(GK) *1533*
Anpec 80(AF) *157*
Antenex 2(AF) *1482*, *1483*, *1643*
Antenex 5(AF) *1482*, *1483*, *1643*
ANTERONE 100(RW)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *459*
.GENITO URINARY SYSTEM AND SEX HORMONES *253*
ANTERONE 50(RW)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *459*
.GENITO URINARY SYSTEM AND SEX HORMONES *253*, *254*
Anthel 125(AF) *1516*
Anthel 250(AF) *1516*
Antroquoril(AL) *224*
Anusol(JT) *1659*
APALUTAMIDE 458
Apidra SoloStar(SW) *72*
Apidra(AV) *72*
Apidra(SW) *72*
APIXABAN 116, 117, 118, 119
APO- Hydroxychloroquine(TX) *1359*
APO- Paracetamol/Codeine 500/30(TX) ..*1416*, *1417*, *1418*
APO-Acamprosate(TX) *1511*
APO-Aciclovir (TX) *303*
APO-Aciclovir(TX) *303*
APO-Alendronate (TX) *1362*, *1363*
APO-Amiodarone(TX) *131*
APO-Amisulpride (TX) *1473*
APO-Amisulpride(TX) *1473*
APO-Amitriptyline 10(TX) *1486*
APO-Amitriptyline 25(TX) *1486*
APO-Amitriptyline 50(TX) *1486*
APO-Amlodipine(TX) *155*
APO-AMOXY/CLAV 500/125(TW) *280*, *281*
APO-AMOXY/CLAV 875/125 (TW) *280*, *281*
APO-Amoxycillin (TX) *274*
APO-Amoxycillin and Clavulanic Acid(TX) *280*, *281*
APO-Amoxycillin(TX) *274*, *275*, *276*
APO-Amoxycillin/ Clavulanic Acid 500/125 (TX) *280*, *281*

APO-Anastrozole(TX) *462*
APO-Aripiprazole(TX) *1473*
APO-Atenolol(TX) *149*, *150*
APO-Atomoxetine(TX) *1496*, *1497*
APO-Atorvastatin(TX) *186*, *187*
APO-Azathioprine(TX) *1349*
APO-Azithromycin(TX)
.Repatriation Pharmaceutical Benefits Scheme *1669*
APO-Azithromycin(TX)
.ANTIINFECTIVES FOR SYSTEMIC USE..... *288*
.SENSORY ORGANS *1540*
APO-Baclofen(TX) *1360*
APO-Bicalutamide(TX) *459*
APO-Bisoprolol(TX) *150*, *151*
APOC-5FU(TX)..... *1670*
APO-Calcitriol(TX)
.ALIMENTARY TRACT AND METABOLISM *102*, *103*
.MUSCULO-SKELETAL SYSTEM *1370*
APO-Candesartan (TX) *169*, *170*
APO-Candesartan HCTZ 16/12.5 (TX) *174*, *175*
APO-Candesartan HCTZ 32/12.5 (TX) *174*, *175*
APO-Candesartan HCTZ 32/25 (TX) *174*, *175*
APO-Carvedilol(TX) *153*, *154*
APO-Cephalexin(TX) *282*, *283*
APO-Ciclosporin(TX) *1230*, *1231*
APO-Ciprofloxacin(TX) *293*, *294*
APO-Citalopram(TX)..... *1488*
APO-Clindamycin(TX) *290*
APO-Clomipramine(TX)..... *1487*
APO-Clonidine(TX) *140*
APO-Clotrimazole 3 Day Cream(TX) *1664*
APO-Clotrimazole 6 Day Cream(TX) *1665*
APO-Desvenlafaxine MR(TX) *1492*, *1493*
APO-Diazepam (TX).....*1482*, *1483*, *1643*
APO-Diazepam(TX).....*1482*, *1483*, *1643*
APO-Diclofenac(TX) *1353*, *1354*
APO-DIMETHYL FUMARATE(XT) *1349*, *1350*
APO-DOMPERIDONE(TX) *51*
APO-Donepezil(TX) *1502*, *1503*
APO-Duloxetine(TX) *1493*
APO-Dutasteride(TX).....*256*, *1668*, *1669*
APO-Enalapril (TX) *158*
APO-Eplerenone(TX)..... *145*, *146*
APO-Escitalopram(TX) *1488*, *1489*
APO-Esomeprazole(TY) *37*, *38*, *39*, *40*
APO-Exemestane(TX) *462*, *463*
APO-Ezetimibe(TX) *201*, *202*
APO-Ezetimibe/Simvastatin 10/10(TX)..... *216*, *217*
APO-Ezetimibe/Simvastatin 10/20(TX)..... *216*, *217*
APO-Ezetimibe/Simvastatin 10/40(TX)..... *215*, *218*
APO-Ezetimibe/Simvastatin 10/80(TX)..... *215*, *217*
APO-Famciclovir(TX)..... *303*, *304*, *305*
APO-Fenofibrate(TX)..... *191*
APO-Fentanyl(TX) *1405*, *1407*, *1409*, *1410*, *1412*, *1636*, *1637*, *1638*
APO-Finasteride(TX) *1669*
APO-Flecainide(TX)..... *131*
APO-Fluoxetine(TX) *1490*
APO-Fluvoxamine(TX)..... *1490*
APO-Fosinopril(TX) *159*
APO-Frusemide(TX) *144*, *145*
APO-Galantamine MR(TX) *1504*
APO-Gliclazide MR(TX)..... *75*
APO-Gliclazide(TX) *75*, *76*
APOHEALTH Macrogol with Electrolytes(GX) *60*, *1623*
APOHEALTH Osteo Relief Paracetamol 665 mg(TX) *1425*, *1641*
APO-Ibuprofen 400(TX) *1356*, *1624*
APO-Imiquimod (TX) *236*, *1664*
APO-Indapamide SR(TX) *144*
APO-Irbesartan (TX).....*171*, *172*
APO-Irbesartan HCTZ (TX).....*175*, *176*
APO-Isosorbide Mononitrate(TX) *133*, *134*
APO-Isotretinoin(TX) *232*
APO-Itraconazole(TX) *298*
APO-Ivabradine(TX) *136*
APO-Lansoprazole ODT(TX).....*41*, *42*, *43*
APO-Lansoprazole(TX) *41*, *42*, *43*
APO-Latanoprost(TX).....*1550*, *1551*
APO-Latanoprost/Timolol 0.05/5(TX) *1551*
APO-LEFLUNOMIDE(TX) *1347*, *1348*
APO-Levetiracetam(TX) *1448*, *1449*, *1450*
APO-Levodopa/Carbidopa(TX) *1458*
APO-Levothyroxine(XT) *267*, *268*
APO-Lisinopril(TX).....*159*
APO-Lurasidone(TX).....*1467*
APO-MACROGOL plus ELECTROLYTES (TX) *60*, *1623*
APO-Mebeverine(TX).....*1653*
APO-Meloxicam(TX).....*1355*
APO-Memantine(TX).....*1507*
APO-Metformin XR 1000(TX).....*74*, *75*
APO-Metformin XR 500(TX).....*74*, *75*
APO-Metoclopramide(TX) *51*, *1622*
APO-Metoprolol(TX).....*152*
Apomine Intermittent(IT).....*1461*
Apomine Solution for Infusion(IT) *1461*
APO-Modafinil(TX) *1502*
APOMORPHINE 1460, 1461
APO-Moxonidine(TX) *142*
APO-Mupirocin(TX) *1662*
APO-Mycophenolate(TX) *479*
APO-Nebivolol(TX).....*153*
APO-Nicorandil(TX).....*134*
APO-Nifedipine XR (TX).....*156*, *157*
APO-Norfloxacin(TX).....*294*
APO-Olanzapine ODT(TX).....*1469*, *1470*
APO-OLANZAPINE(TX) *1468*, *1469*
APO-Olmesartan(TX) *172*, *173*
APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5(TX) *184*
APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5(TX) *184*, *185*
APO-Olmesartan/Amlodipine/HCTZ 40/10/25(TX) .*184*, *185*
APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet(TX) *184*, *185*
APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet(TX) *184*, *185*
APO-Olmesartan/HCTZ 20/12.5(TX).....*176*, *177*
APO-Olmesartan/HCTZ 40/12.5(TX).....*177*
APO-Olmesartan/HCTZ 40/25(TX).....*177*
APO-Omeprazole(TX) *43*, *44*, *45*
APO-Ondansetron(TX) *52*, *53*
APO-Oxazepam (TX) *1483*, *1484*, *1643*
APO-Pantoprazole(TX).....*46*, *47*, *48*
APO-Paracetamol(TX).....*1424*, *1425*, *1673*
APO-Paroxetine(TX).....*1491*
APO-Perindopril Arginine(TX) *159*, *160*, *161*
APO-Perindopril Arginine/Amlodipine 10/10(TX) *167*, *168*
APO-Perindopril Arginine/Amlodipine 10/5(TX) *167*, *168*
APO-Perindopril Arginine/Amlodipine 5/10(TX) *167*, *168*
APO-Perindopril Arginine/Amlodipine 5/5(TX) *167*, *168*
APO-Perindopril(TX).....*160*, *161*
APO-Perindopril/Indapamide(TX).....*166*
APO-Piroxicam(TX).....*1355*, *1356*
APO-Pramipexole ER(TX).....*1463*
APO-Pramipexole(TX).....*1462*, *1463*, *1464*
APO-Prazosin(TX).....*142*, *143*
APO-Pregabalin(TX).....*1425*, *1426*
APO-Prochlorperazine(TX).....*56*, *57*
APO-Propranolol(TX) *149*
APO-Quinapril (TX) *161*

APO-Rabeprazole(TX) *48*, *49*, *50*
APO-Ramipril(TX) *162*, *163*
APO-Ranitidine(TX) *37*
APO-Riluzole(TX) *1512*
APO-Risedronate (TX) *1364*, *1365*
APO-Risedronate(TX) *1365*, *1671*
APO-Risperidone(TX) *1476*, *1477*, *1478*, *1479*, *1480*, *1481*, *1482*
APO-Rizatriptan(TX) *1428*
APO-ROSUVASTATIN(TX) *189*, *190*
APO-Roxithromycin(TX) *289*, *290*
Aporyl(TX) *1659*
APO-Sertraline(TX) *1491*
APO-Simvastatin(TX) *190*, *191*
APO-Sodium Valproate(TX) *1437*, *1438*
APO-Sumatriptan(TX) *1428*
Apo-Tadalafil(TX) *1666*
Apo-Tamsulosin SR(TX) *1668*
APO-Telmisartan HCTZ 40/12.5(TX) *177*, *178*
APO-Telmisartan HCTZ 80/12.5(TX) *178*
APO-Telmisartan HCTZ 80/25(TX) *178*
APO-Telmisartan(TX) *173*
APO-Temazepam(TX) *1484*, *1485*, *1643*
APO-Temozolomide(TX) *314*
APO-Terbinafine(TX) *220*, *1660*
APO-TERIFLUNOMIDE(TX) *1349*
APOTEX-Pioglitazone (TX) *88*, *89*
APO-Topiramate(TX) *1454*, *1455*, *1456*
APO-Tramadol SR(TX) *1423*, *1424*
APO-Tramadol(TX) *1420*, *1421*, *1422*
APO-Tranexamic Acid(TX) *126*
APO-Ursodeoxycholic acid(TX) *58*
APO-Venlafaxine XR(TX) *1494*, *1495*
APO-Zolmitriptan(TX) *1428*
APO-Zopiclone(TX) *1674*
APREMILAST 477
APREPITANT 54
Aprepitant APOTEX(TX) *55*
APREPITANT SCP (XC) *55*
Aptamil Gold+ Pepti-Junior(NU) *1594*
APX-Amitriptyline (TY) *1486*
APX-AMLODIPINE (TW) *155*
APX-Amoxicillin/Clavulanic Acid (XT) *280*, *281*
APX-Amoxicillin/Clavulanic Acid(XT) *280*, *281*
APX-Atenolol (TY) *149*, *150*
APX-Celecoxib(TW) *1359*
APX-Ciprofloxacin (TY) *293*, *294*
APX-Citalopram (TY) *1488*
APX-Clopidogrel/Aspirin 75/100(TY) *112*, *113*
APX-Diazepam (TY) *1482*, *1483*, *1643*
APX-Diazepam(TY) *1482*, *1483*, *1643*
APX-Doxycycline(TX) *272*, *273*
APX-Escitalopram (TY) *1488*, *1489*
APX-Gabapentin(GX)
.Repatriation Pharmaceutical Benefits Scheme *1673*
APX-Gabapentin(GX)
.NERVOUS SYSTEM *1441*
APX-Gliclazide (TY) *75*, *76*
APX-Lamotrigine(TY) *1447*, *1448*
APX-Meloxicam(TY) *1355*
APX-Metformin(TY) *74*, *75*
APX-Mirtazapine(TY) *1494*
APX-Olmesartan (TY) *172*, *173*
APX-Olmesartan/HCTZ (TY) *176*, *177*
APX-Ondansetron (TY) *52*, *53*
APX-Ondansetron ODT(TY) *53*, *54*
APX-PANTOPRAZOLE (TW) *46*, *47*, *48*
APX-Paracetamol/Codeine (TY) *1416*, *1417*, *1418*
APX-Paroxetine (TY) *1491*
APX-Perindopril Arginine (XT) *159*, *160*, *161*
APX-Perindopril Arginine/Amlodipine 10/10 (XT) *167*, *168*
APX-Perindopril Arginine/Amlodipine 10/5 (XT) *167*, *168*
APX-Perindopril Arginine/Amlodipine 5/10 (XT) *167*, *168*
APX-Perindopril Arginine/Amlodipine 5/5 (XT) *167*, *168*
APX-Pravastatin(TY) *188*
APX-Quetiapine XR(TY) *1471*, *1472*
APX-QUETIAPINE(TX) *1471*, *1472*
APX-Ramipril (TY) *162*, *163*
APX-Rosuvastatin (TY) *189*, *190*
APX-Rosuvastatin(TY) *189*, *190*
APX-Roxithromycin (TY) *289*, *290*
APX-Sotalol(TY) *131*
APX-Valaciclovir(TY) *308*
Aquacare H.P.(VE) *1660*
Aquacel 403770(CC) *1694*
Aquacel Ag 403708(CC) *1694*
Aquacel Ag 403710(CC) *1694*
Aquacel Ag 403771(CC) *1694*
Aquacel Extra 420672(CC) *1694*
Aquacel Extra 420673(CC) *1694*
Aquacel Foam Adhesive(CC) *1694*
Aquacel Foam Non-Adhesive(CC) *1694*
Aquasun Lotion SPF 18(PF) *1661*
Arabloc (AV) *1347*, *1348*
ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE 1612
Aratac 100(AF) *131*
Aratac 200 (AF) *131*
Arava (SW) *1347*, *1348*
Arava(SW) *1347*, *1348*
Arazil (AF) *1502*, *1503*
ARDIX GLICLAZIDE 60mg MR(XT) *75*, *76*
Arginine 2000(VF) *1612*
Arginine 500(VF) *1612*
Arginine 5000(VF) *1612*
ARGININE WITH CARBOHYDRATE 1612
Arianna 1 (AF) *462*
Aricept(PF) *1502*, *1503*
Aridon 10(RW) *1502*, *1503*
Aridon 5(RW) *1502*, *1503*
Aridon APN 10 (RF) *1502*, *1503*
Aridon APN 5 (RF) *1502*, *1503*
Aripic Aripiprazole (LR) *1473*
ARIPIPRAZOLE 1473
Aripiprazole GH (GQ) *1473*
Aripiprazole GH(GQ) *1473*
Aripiprazole Sandoz (SZ) *1473*
Aripiprazole Sandoz(SZ) *1473*
Aristocort 0.02%(AS) *222*
Arixtra(AS) *125*
ARIZOLE (RW) *1473*
ARIZOLE(RW) *1473*
ARMODAFINIL 1495
Arnuity Ellipta(GK) *1534*
Aromasin(PF) *462*, *463*
Aropax(AS) *1491*
Arrow Pharma Pty Ltd(RW) *301*
Artane(RW) *1457*
ARTEMETHER + LUMEFANTRINE 1514, 1515
Arthrexin(AF) *1354*, *1623*
Artige(NM) *1498*
ARX-ACICLOVIR(XT) *303*
ARX-Dabigatran(XT) *115*, *116*
ARX-GLIMEPIRIDE(XT) *76*
ARX-LERCANIDIPINE(TX) *156*
ARX-LETROZOLE(XT) *463*, *464*
ARX-Methotrexate(XT)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *315*, *1350*, *1351*
ARX-MYCOPHENOLATE(XT) *478*, *479*

ARX-NALTREXONE(XT) *1511*
ARX-Nitrofurantoin(XT) *296*
ARX-SEVELAMER(XT) *1578*, *1579*
ARX-Sunitinib(XT) *425*, *426*, *427*, *428*
Asacol(EU) *66*, *68*
ASCIMINIB 321, 322
ASENAPINE 1468
Asmol CFC-Free with dose counter(AF) *29*, *1518*
Aspalgin 40(GO) *1672*
Aspecillin VK(AF) *277*, *278*
Aspen Methadone Syrup(AS)
.Palliative Care *1639*
Aspen Pharma Pty Ltd(AS)
.NERVOUS SYSTEM *1375*, *1376*, *1497*
ASPIRIN 112, 1657
ASPIRIN + CODEINE 1672
Astrix(YN) *1657*
Atacand Plus 16/12.5(LM) *174*, *175*
Atacand Plus 32/12.5(LM) *174*, *175*
Atacand Plus 32/25(LM) *174*, *175*
Atacand(LM) *169*, *170*
Ataris 10 (AF) *1347*, *1348*
Ataris 20(AF) *1347*, *1348*
Atectura Breezhaler(NV) *1529*
ATENOLOL 149, 150
Atenolol GH(GQ) *149*, *150*
Atenolol Sandoz (SZ) *149*, *150*
Atenolol-AFT(AE) *150*
ATOMOXETINE 1496
Atomoxetine Sandoz (SZ) *1496*, *1497*
Atorvachol (RF) *186*, *187*
ATORVASTATIN 186, 187
Atorvastatin GH(GQ) *187*
Atorvastatin SZ (HX) *187*
Atorvastatin SZ(HX) *186*, *187*
ATOVAQUONE 1514
ATOVAQUONE + PROGUANIL 1514
AtovaquoPro Lupin 250/100(GQ) *1514*
Atozet(AF) *211*, *212*, *213*, *214*
Atrauman 499513(HR) *1697*
Atrauman Ag 499572(HR) *1699*
Atrauman Ag 499573(HR) *1699*
Atrauman Silicone 499561(HR) *1698*
Atropine Injection (Pfizer)(WZ) *26*, *50*
ATROPINE SULFATE
.ALIMENTARY TRACT AND METABOLISM 50
.Prescriber Bag 26
.SENSORY ORGANS 1552
Atropt(AS) *1552*
Atrovent Adult(BY) *1536*
Atrovent(BY) *1535*, *1536*
Augmentin Duo 400(AS) *280*, *281*
Augmentin Duo forte(AS) *280*, *281*
Augmentin Duo(AS) *280*, *281*
AURANOFIN 1359
Aurorix 300 mg(GO) *1492*
Aurorix(GO) *1492*
Ausfam 20(RW) *36*
Ausfam 40(RW) *36*
Ausgem(RW) *192*
AVANAFIL 1665
Avanza(AL) *1494*
Avapro HCT 150/12.5(AV) *176*
Avapro HCT 300/12.5(AV) *176*
Avapro HCT 300/25(AV) *176*
Avapro(AV) *171*, *172*
Avodart(GK) *256*, *1668*, *1669*
AVSARTAN HCT 150/12.5(RF) *175*, *176*
AVSARTAN HCT 300/12.5(RF) *176*
AVSARTAN HCT 300/25(RF) *176*
AVSARTAN(RF) *171*, *172*
Axit 15 (AF) *1494*
Axit 30 (AF) *1494*
Axit 45 (AF) *1494*
AXITINIB 402
Axotide Accuhaler(TX) *1534*
Axotide Junior Accuhaler(TX) *1534*
Axotide Junior(TX) *1535*
Axotide(TX) *1534*
AZACITIDINE 315, 316
Azapin (RW) *1349*
Azarga(NV) *1548*
AZATHIOPRINE 1349
Azathioprine Sandoz (SZ) *1349*
Azathioprine Sandoz(SZ) *1349*
Azilect(TB) *1464*
AZITHROMYCIN
.ANTIINFECTIVES FOR SYSTEMIC USE 288
.Repatriation Pharmaceutical Benefits Scheme 1669
.SENSORY ORGANS 1540
Azithromycin Mylan (AF) *288*, *1540*, *1669*
Azithromycin Sandoz(SZ)
.Repatriation Pharmaceutical Benefits Scheme *1669*
Azithromycin Sandoz(SZ)
.ANTIINFECTIVES FOR SYSTEMIC USE *288*
.SENSORY ORGANS *1540*
Azithromycin Viatris (AL)
.ANTIINFECTIVES FOR SYSTEMIC USE *288*
.SENSORY ORGANS *1540*
Azopt(NV) *1547*, *1548*
BACLOFEN 1360
Bactigras 7457(SN) *1690*
Bactrim DS(XO) *287*, *288*
Bactroban(GK)
.Repatriation Pharmaceutical Benefits Scheme *1662*
Bactroban(GK)
.RESPIRATORY SYSTEM *1517*
BALSALAZIDE 65, 66
BANDAGE ABSORBENT WOOL 1678
BANDAGE CALICO 1678
BANDAGE COMPRESSION 1678, 1679
BANDAGE RETENTION COHESIVE HEAVY 1679
BANDAGE RETENTION COHESIVE LIGHT 1680
BANDAGE RETENTION COTTON CREPE 1680
BANDAGE TUBULAR 1680
BANDAGE TUBULAR FINGER 1681
BANDAGE TUBULAR LIGHT WEIGHT 1681
BANDAGE TUBULAR LONG STOCKING 1681
BANDAGE TUBULAR SHORT STOCKING 1681
BANDAGE ZINC PASTE 1682
BARICITINIB 1239, 1241, 1244
basecal 200(VF) *1612*
Baxter Healthcare Pty Ltd(BX) *1659*
BECLOMETASONE 1533
BECLOMETASONE + FORMOTEROL 1519
BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM 1529, 1530
Bemfola(FX) *251*
BEMOTRIZINOL + DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE + HOMOSALATE + OCTOCRYLENE + TITANIUM DIOXIDE 1661
BenPen(CS) *26*, *276*
BENZATHINE BENZYLPENICILLIN 26, 276
BENZATROPINE 26, 1458
Benzatropine Injection(FF) *26*, *1458*
Benztrop(FF) *1458*
BENZYDAMINE 36, 1622
BENZYLPENICILLIN 26, 276
Beovu(NV) *1558*
Betadine Antiseptic Liquid(SW) *1662*

Betaferon(BN) *466*
BETAINE 105
BETAINE + POLYAMINOPROPYL BIGUANIDE 1682
Betaloc(AP) *152*
BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE 261
BETAMETHASONE DIPROPIONATE 222, 223, 224
BETAMETHASONE VALERATE 224, 225, 1662
Betavit(PP) *103*, *104*, *1655*, *1656*
BETAXOLOL 1549
BETHANECHOL 1508
Betnovate 1/2(AS) *224*, *225*, *226*
Betnovate 1/5(AS) *224*
Betnovate(AS) *1662*
Betoptic(NV) *1549*
BetoQuin(NM) *1549*
Bi ELIGARD CP(MF) *454*, *455*
Biatain Adhesive 3420(CT) *1692*
Biatain Adhesive 3423(CT) *1692*
Biatain Ag 9622(CT) *1700*
Biatain Ag 9632(CT) *1700*
Biatain Non-adhesive 3410(CT) *1692*
Biatain Non-adhesive 3413(CT) *1692*
Bicalox (ZS) *459*
BICALUTAMIDE 458
BICARBONATE 255
BICARBONATE + CITRIC ACID + TARTARIC ACID .. 1666
Bicard 10 (RW) *150*, *151*
Bicard 2.5 (RW) *150*, *151*
Bicard 5 (RW) *150*, *151*
Bicillin L-A(PF) *26*, *276*
Bicor(AL) *150*, *151*
Biltricide(BN) *1515*
BIMATOPROST 1549, 1550
BIMATOPROST + TIMOLOL 1550
Bimatoprost Sandoz(SZ) *1549*, *1550*
BIMEKIZUMAB 1042, 1049
Bimprozt (TY) *1549*, *1550*
Bimtop(AF) *1550*
Bimzelx(UC) *1049*, *1054*
BINIMETINIB 388
BiResp Spiromax(TB) *1520*, *1522*, *1523*, *1525*
BISACODYL 59, 1653
BISOPROLOL 150
Bisoprolol generichealth(GQ) *150*, *151*
Bisoprolol Sandoz (SZ) *150*, *151*
Bispro 10(AF) *150*, *151*
Bispro 2.5(AF) *150*, *151*
Bispro 5(AF) *150*, *151*
BIVALIRUDIN 114
Bivalirudin APOTEX(TX) *114*
BIVALIRUDIN ARX (XT) *114*
Blooms Amlodipine (BG) *155*
Blooms Amlodipine(BG) *155*
Blooms Clopidogrel(BG) *112*
Blooms Escitalopram(BG) *1488*, *1489*
Blooms Irbesartan (BG) *171*, *172*
Blooms Rosuvastatin (BG) *189*, *190*
Blooms Rosuvastatin(BG) *189*, *190*
Blooms the Chemist Amlodipine (IB) *155*
Blooms the Chemist Amlodipine(IB) *155*
Blooms The Chemist Amoxicillin (BG) *274*, *275*, *276*
Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 (BG) *280*, *281*
Blooms The Chemist Atenolol(BG) *149*, *150*
Blooms the Chemist Atorvastatin (IB) *186*, *187*
Blooms the Chemist Atorvastatin(IB) *187*
Blooms the Chemist Candesartan HCTZ 16/12.5(IB) ... *174*, *175*
Blooms the Chemist Candesartan HCTZ 32/12.5(IB) *174*, *175*
Blooms the Chemist Candesartan HCTZ 32/25(IB) *174*, *175*
Blooms the Chemist Candesartan(IB) *169*, *170*
Blooms The Chemist Cefalexin (BG) *282*, *283*
Blooms the Chemist Celecoxib (IB) *1359*
Blooms the Chemist Escitalopram (IB) *1488*
Blooms The Chemist Ezetimibe (IB) *201*, *202*
Blooms the Chemist Fenofibrate (IB) *191*
Blooms the Chemist Fluoxetine (BG) *1490*
Blooms the Chemist Irbesartan HCTZ 150/12.5 (IB) *175*, *176*
Blooms the Chemist Irbesartan HCTZ 300/12.5 (IB) *176*
Blooms the Chemist Irbesartan HCTZ 300/25 (IB) *176*
Blooms the Chemist Irbesartan(IB) *171*, *172*
Blooms The Chemist Metformin 1000 mg (BG) *74*
Blooms The Chemist Metformin 500 mg (BG) *74*, *75*
Blooms The Chemist Metformin 850 mg (BG) *74*, *75*
Blooms the Chemist Metformin XR 1000 (IB) *74*, *75*
Blooms the Chemist Metformin XR 500 (IB) *74*, *75*
Blooms The Chemist Mirtazapine(BG) *1494*
Blooms The Chemist Olmesartan(BG) *172*, *173*
Blooms The Chemist Paroxetine(BG) *1491*
Blooms the Chemist Perindopril (IB) *160*, *161*
Blooms The Chemist Pregabalin (IB) *1425*, *1426*
Blooms The Chemist Quetiapine (BG) *1471*, *1472*
Blooms the Chemist Rosuvastatin (IB) *189*, *190*
Blooms the Chemist Rosuvastatin(IB) *189*, *190*
Blooms the Chemist Tamsulosin SR (IB) *1668*
Blooms the Chemist Venlafaxine XR (IB) *1494*, *1495*
Bondronat(IX) *1363*
B-Patch(IU) *1416*, *1641*
Braftovi(FB) *382*, *383*
Braltus(TB) *1537*
Brenzys(RF) .. *853*, *860*, *862*, *864*, *869*, *871*, *879*, *880*, *882*, *894*, *904*, *914*, *917*, *921*, *922*, *925*, *934*, *952*, *957*, *977*
Breo Ellipta 100/25(GK) *1526*
Breo Ellipta 200/25(GK) *1525*
Bretaris Genuair(FK) *1535*
Brevactid 1500 I.E(DZ) *252*
BREXPIPRAZOLE 1474
Breztri Aerosphere(AP) *1530*
Bricanyl Turbuhaler(AP) *1519*
Bricanyl(AP) *1538*
BRIGATINIB 384, 385
Brilinta(AP) *113*
Brimica Genuair(FK) *1529*
BRIMONIDINE 1546
BRIMONIDINE + TIMOLOL 1546, 1547
BRINZOLAMIDE 1547
BRINZOLAMIDE + BRIMONIDINE 1548
BRINZOLAMIDE + TIMOLOL 1548
BrinzoQuin(NM) *1547*, *1548*
BRIVARACETAM 1439, 1440
Briviact(UC) *1439*, *1440*
BROLUCIZUMAB 1557
BROMAZEPAM 1674
BROMOCRIPTINE
.GENITO URINARY SYSTEM AND SEX HORMONES 236, 237
.NERVOUS SYSTEM 1461
Brufen(GO) *1356*, *1624*
Brukinsa(IE) *406*, *407*, *408*
BSN 2902165(BV) *1700*
BTC Amlodipine (JB) *155*
BTC Amlodipine(JB) *155*
BTC Atorvastatin (BG) *187*
BTC Atorvastatin(BG) *186*, *187*
BTC Candesartan (BG) *169*, *170*
BTC Candesartan HCT (BG) *174*, *175*

BTC Clopidogrel(JB) *112*, *1658*
BTC Desvenlafaxine(BG) *1492*, *1493*
BTC Ezetimibe(BG) *201*, *202*
BTC Fenofibrate(BG) *191*
BTC Fluoxetine(JB) *1490*
BTC Lercanidipine (JB) *156*
BTC Pantoprazole (BG) *46*
BTC Pantoprazole(BG) *46*, *47*, *48*
BTC Perindopril(JB) *160*, *161*
BTC Pregabalin(BG) *1425*, *1426*
BTC Tamsulosin SR(BG) *1668*
Budamax Aqueous(JT) *1676*
Budenofalk(FD) *63*
BUDESONIDE
.ALIMENTARY TRACT AND METABOLISM 63, 64
.Repatriation Pharmaceutical Benefits Scheme 1676
.RESPIRATORY SYSTEM 1533, 1534
BUDESONIDE + FORMOTEROL ..1520, 1521, 1522, 1523, 1524
BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL 1530
Bufomix Easyhaler 200/6(OX) *1520*, *1522*, *1523*
Bufomix Easyhaler 400/12(OX) *1525*
Bupredermal (TX) *1416*, *1641*
Bupredermal(TX) *1416*, *1641*
BUPRENORPHINE
.NERVOUS SYSTEM 1414
.Palliative Care 1640
Buprenorphine Sandoz (SZ) *1416*, *1641*
Buprenorphine Sandoz(SZ) *1416*, *1641*
BUPROPION 1508
Buscopan(VZ) *27*, *1622*, *1653*
BUSULFAN 313
Cabaser(PF) *1462*
CABERGOLINE
.GENITO URINARY SYSTEM AND SEX HORMONES 238
.NERVOUS SYSTEM 1462
Cabometyx(IS) *409*, *410*
CABOZANTINIB 409, 410
CADEXOMER-IODINE 1682
Cadivast 10/10(AF) *218*
Cadivast 10/20(AF) *218*
Cadivast 10/40(AF) *218*
Cadivast 10/80(AF) *218*
Cadivast 5/10(AF) *218*, *219*
Cadivast 5/20(AF) *218*, *219*
Cadivast 5/40(AF) *218*, *219*
Cadivast 5/80(AF) *218*, *219*
Caduet 10/10(AS) *218*
Caduet 10/20(AS) *218*
Caduet 10/40(AS) *218*
Caduet 10/80(AS) *218*, *219*
Caduet 5/40(AS) *218*, *219*
Caduet 5/80(AS) *218*, *219*
Cal-500(PP) *104*, *1656*, *1657*
CAL-600(PP) *1656*, *1657*
Cal-care 600 mg(CR) *1656*, *1657*
CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE 221
Calcipotriol/Betamethasone Sandoz 50/500(SZ) *221*
Calciprox (ZS) *102*, *103*, *1370*
Calci-Tab 600(AE) *104*
CALCITONIN SALMON 271
CALCITRIOL
.ALIMENTARY TRACT AND METABOLISM 102, 103
.MUSCULO-SKELETAL SYSTEM 1369, 1370
CALCIUM 104, 1656, 1657
Calindamin (RW) *290*
CALITROL(XT)
.ALIMENTARY TRACT AND METABOLISM *102*, *103*
.MUSCULO-SKELETAL SYSTEM *1370*
CALQUENCE(AP) *403*, *404*, *405*
Calutex(AS) *459*
Camino Pro Bettermilk(QH) *1614*
Camino Pro Complete(QH) *1614*
Campral (AF) *1511*
Camzyos(BQ) *137*, *138*, *140*
CANDESAN COMBI 16/12.5(RF) *174*, *175*
CANDESAN COMBI 32/12.5(RF) *174*, *175*
CANDESAN COMBI 32/25(RF) *174*, *175*
CANDESAN(RF) *169*, *170*
CANDESARTAN 169, 170
CANDESARTAN + HYDROCHLOROTHIAZIDE 174
Candesartan Sandoz (SZ) *169*, *170*
Candesartan/HCT Sandoz (SZ) *174*, *175*
CANNABIDIOL 1440
CAPECITABINE 317
Capecitabine Alphapharm(AF) *317*
Capecitabine Sandoz(SZ) *317*
Capecitabine-DRLA (RZ) *317*
Capoten(RW) *158*
CAPTOPRIL 158
CARBAMAZEPINE 1434, 1435
Carbamazepine Sandoz(NM) *1434*, *1435*
CARBAMIDE PEROXIDE 1677
CARBIMAZOLE 269
CarboFLEX 403202(CC) *1683*
CarboFLEX 403204(CC) *1683*
Carbohydrate Free Mixture(SB) *1617*
CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS 1612
CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID 1612
CARBOMER-980 ..... 1566, 1567
Cardasa(AF) *1658*
Cardiprin 100(RC) *1657*
Cardizem CD(SW) *157*, *158*
Cardizem(SW) *158*
Cardol (AF) *131*
CARIPRAZINE 1474
Carlevent(TX) *1460*
CARMELLOSE SODIUM 1567, 1568
CARMELLOSE SODIUM + GLYCEROL 1568
CARMUSTINE 313
Cartia(AS) *1658*
CARVEDILOL 153, 154
Carvedilol Sandoz (SZ) *153*, *154*
Carvidol (RF) *154*
Carvidol(RF) *153*, *154*
Catapres 100 (IX) *140*
Catapres(IX) *140*, *141*
Cationorm(CS) *1572*
Caverject Impulse(PF) *1665*
Cavicare 4563(SN) *1686*
Cavstat (AF) *189*, *190*
Cavstat(AF) *189*, *190*
Ceclor CD(AL) *285*
Ceclor(AL) *284*, *285*
CEFACLOR 284
Cefaclor SUN (RA) *284*, *285*
CEFALEXIN 282, 283
Cefalexin Sandoz(SZ) *282*, *283*
CEFAZOLIN 283, 284
Cefazolin-AFT(AE) *283*, *284*
CEFEPIME 287
Cefepime Kabi(PK) *287*
CEFOTAXIME 285

CEFTRIAXONE 286
Ceftriaxone Viatris(AL) *286*
Ceftriaxone-AFT(AE) *286*
CEFUROXIME 285
Celapram (AF) *1488*
Celapram(AF) *1488*
Celaxib(AF) *1359*
Celebrex (UJ) *1359*
CELECOXIB 1358
Celecoxib APOTEX(TY) *1359*
Celecoxib GH (GQ) *1359*
Celecoxib Sandoz(SZ) *1359*
Celestone Chronodose(OQ) *261*, *262*
Celestone-M(AF) *224*
Celexi (RW) *1359*
CellCept (RO) *478*, *479*
CellCept(RO) *478*
Cellufresh(VE) *1567*, *1568*
Celluvisc(VE) *1567*
Cephalex 500 (CR) *282*, *283*
Cephalexin generichealth(GQ) *282*, *283*
Cephazolin Alphapharm(AF) *284*
Cephazolin Viatris (AL) *284*
Ceptolate(AF) *478*, *479*
Cequa(RA) *1570*
CERITINIB 385
Certican(NV) *1345*, *1346*
CERTOLIZUMAB PEGOL 820, 821, 822, 824, 826, 827, 829, 831, 834, 836, 840, 843, 847
Cerumol(UN) *1677*
CETIRIZINE 1676
C-Flox 250(AL) *294*
C-Flox 500(AL) *293*
C-Flox 750(AL) *293*
Champix(PF) *1510*, *1511*
Chemists' Own Laxative with Senna(RW) *1654*
Chemists' Own Macrogol with Electrolytes(RW) *61*, *1623*
Chexate (OX) *315*, *1350*, *1351*
CHLORAMBUCIL 313
CHLORAMPHENICOL 1540, 1677
CHLORHEXIDINE 1653
CHLORPROMAZINE 26, 1465
Chlorsig(AS) *1540*, *1677*
CHLORTALIDONE 144
Chlorvescent(AS) *105*
Cholestyramine (Ascend, USA)(CR) *192*
Cholestyramine-Odan(DZ) *192*
Cholstat 10(AF) *188*
Cholstat 20 (AF) *188*
Cholstat 40 (AF) *188*
CHORIOGONADOTROPIN ALFA 250
Cialis (LY) *1666*
CICLESONIDE 1534
CICLOSPORIN
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 1230
.SENSORY ORGANS 1568
Cidala(RW) *1666*
Cifran (RA) *293*
Cilamox (AL) *274*, *275*, *276*
Cilamox(AL) *274*, *275*, *276*
Cilatil (AF) *1666*
Cilicaine V(AF) *277*
Cilicaine VK(AF) *277*, *278*
Cilopam-S(ZS) *1488*
CiloQuin(NM) *1541*
Ciloxan(NV)
.SENSORY ORGANS *1541*, *1574*
Cimzia(UC) *821*, *822*, *824*, *826*, *827*, *829*, *831*, *834*, *836*, *840*, *843*, *847*, *851*
CINACALCET 271
Cinacalcet Mylan(AF) *271*
Cinacalcet Viatris (AL) *271*
Cinacalcet Viatris(AL) *271*
Cipla Bisoprolol (LR) *150*, *151*
Cipla Gefitinib(LR) *378*
Cipla Icatibant(LR) *128*
CIPLA MELOXICAM 15 (LR) *1355*
CIPLA MELOXICAM 7.5 (LR) *1355*
Cipla Pregabalin (LR) *1425*, *1426*
Cipla Tadalafil(LR) *1666*
CIPLA TENOFOVIR + EMTRICITABINE 300/200(LR) ... *313*
Cipramil(LU) *1488*
CIPROFLOXACIN
.ANTIINFECTIVES FOR SYSTEMIC USE 292, 293
.SENSORY ORGANS 1541, 1574
Ciprofloxacin Sandoz (SZ) *293*, *294*
Ciprofloxacin Sandoz(SZ) *293*
Ciprol 250(RW) *294*
Ciprol 500 (RW) *293*
Ciprol 750(RW) *293*
CITALOPRAM 1488
Citalopram Sandoz (SZ) *1488*
Citalopram Sandoz(SZ) *1488*
CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL 61, 1623, 1654
CITRULLINE 1612
Citrulline 1000(VF) *1613*
Citrulline Easy(OH) *1613*
CITRULLINE WITH CARBOHYDRATE 1613
CLADRIBINE
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 477
Claratyne(BN) *1676*
Clarithro 250(RW) *288*
CLARITHROMYCIN 288
Clarithromycin Sandoz (SZ) *288*
Clexane Forte Safety-Lock(AV) *111*
Clexane Safety-Lock(AV) *111*
CLINDAMYCIN 290
Clindamycin LU(XT) *290*
Clindamyk (AF) *290*
Clobemix (XT) *1492*
CLOBETASOL 231
Clobex(GA) *231*
Clofen 10 (AF) *1360*
Clofen 25 (AF) *1360*
Clomid(SW) *253*
CLOMIFENE 252
CLOMIPRAMINE 1486
Clonac 25 (RW) *1353*, *1354*
Clonac 50 (RW) *1354*
CLONAZEPAM 26, 1433, 1434, 1642
Clonea 3 Day Cream (AF) *1664*
Clonea 6 Day Cream(AF) *1665*
Clonea(AF) *1659*
CLONIDINE 140
Clonidine Lupin(GQ) *140*, *141*
CLOPIDOGREL 112, 1658
CLOPIDOGREL + ASPIRIN 112
Clopidogrel Lupin (GQ) *112*
Clopidogrel Lupin(GQ) *1658*
Clopidogrel Sandoz Pharma (HX) *1658*
Clopidogrel Sandoz Pharma(HX) *112*
Clopidogrel Winthrop (WA) *112*
Clopidogrel Winthrop plus aspirin (WA) *112*, *113*
Clopixol Depot(LU) *1468*
CLOTRIMAZOLE
.Repatriation Pharmaceutical Benefits Scheme 1659, 1664

Clovix 75 (RW) *112*
COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR 1661
COAL TAR SOLUTION + SALICYLIC ACID 1663
Cobal-B12(JU) *127*
Coban 1584(MM) *1679*
Coban 2(MM) *1679*
COBIMETINIB 388
Codalgin Forte(AF) *1416*, *1417*, *1418*
Codapane Forte 500/30 (AL) *1416*, *1417*, *1418*
CODEINE 1375
Co-Diovan 160/12.5(NV) *178*, *179*
Co-Diovan 160/25(NV) *178*, *179*
Co-Diovan 320/12.5(NV) *179*
Co-Diovan 320/25(NV) *179*
Co-Diovan 80/12.5(NV) *178*, *179*
Colaxsen (AS) *1654*
Colazide(PK) *66*
COLCHICINE 1362
Colcine(CR) *1362*
Colese (AF) *1653*
COLESTYRAMINE 192
Colgout(AS) *1362*
Colifoam(GO) *65*
Colofac(GO) *1653*
Coloxyl 50(AS) *1653*
Coloxyl with Senna(LN) *1654*
Combigan(VE) *1547*
Comfarol Forte(SZ) *1416*, *1417*, *1418*
Comfeel Plus Pressure Relieving 3350(CT) *1694*
Comfeel Plus Pressure Relieving 3353(CT) *1694*
Comfeel Plus Transparent 3530(CT) *1693*
Comfeel Plus Transparent 3533(CT) *1693*
Comfeel Plus Transparent 3536(CT) *1693*
Comfeel Plus Ulcer Dressing 3110(CT) *1694*
Comfeel Purilon Gel 3900(CT) *1695*
Comfeel SeaSorb Dressing 3705(CT) *1684*
Comfeel SeaSorb Dressing 3710(CT) *1684*
Comfeel SeaSorb Filler 3740(CT) *1683*
Comprilan 01027-00(BV) *1678*
Comtan(SZ) *1465*
Concerta(JC) *1499*
Copaxone(TB) *467*
Coralan (SE) *136*
Corbeton 40(AF) *149*
Cordarone X 100 (SW) *131*
Cordarone X 200(SW) *131*
Cordilox 180 SR(GT) *157*
Cordilox SR(GT) *157*
Cortate(AS) *262*
Cortic-DS 1%(AS) *1662*
Cortic-DS 1%(LN) *222*
CORTISONE 262
Cortival 1/2(LN) *224*, *225*, *226*
Cortival 1/5(LN) *224*
Cosamide 50 (AF) *459*
Cosdor(AF) *1549*
Co-Senna (PP) *1654*
Cosentyx(NV) ..*1100*, *1102*, *1104*, *1106*, *1108*, *1109*, *1111*, *1114*, *1117*, *1120*, *1123*, *1126*, *1130*, *1134*, *1139*
Cosopt(MF) *1549*
Cosudex(AP) *459*
Cotellic(RO) *388*, *389*
Coumadin(GO) *110*
Coveram 10/10(SE) *167*, *168*
Coveram 10/5(SE) *167*, *168*
Coveram 5/10(SE) *167*, *168*
Coveram 5/5(SE) *168*
Coversyl 10mg(SE) *160*, *161*
Coversyl 2.5mg(SE) *160*, *161*
Coversyl 5mg(SE) *160*
Coversyl Plus 5mg/1.25mg(SE) *166*
Coversyl Plus LD 2.5mg/0.625mg(SE) *165*
Creon 10,000(GO) *71*
Creon 25,000(GO) *71*
Creon 35,000(GO) *71*
Creon Micro(GO) *71*
Crestor(FK) *189*, *190*
CRIZOTINIB 386
CROMOGLYCATE 1676
Crosuva 10 (RW) *189*
Crosuva 20 (RW) *189*
Crosuva 40 (RW) *189*, *190*
Crosuva 5(RW) *189*, *190*
Crysanal(IY) *1358*, *1624*
Cubitan(SB) *1677*
Curam Duo 500/125(SZ) *280*, *281*
Curam Duo Forte 875/125(SZ) *280*, *281*
Curam Duo(SZ) *280*, *281*
Curam(SZ) *280*, *281*
Curity 4112(KE) *1690*
Cutifilm Plus 36361370(SN) *1685*
Cutifilm Plus 36361371(SN) *1685*
Cutilin Non-Stick Wound Pad 36361374(SN) *1697*
Cutilin Non-Stick Wound Pad 36361375(SN) *1697*
Cutinova Hydro 66047441(SN) *1692*
Cutinova Hydro 66047443(SN) *1692*
Cyclonex(GH) *313*
CYCLOPHOSPHAMIDE 313
Cyclosporin Sandoz (NM) *1230*, *1231*
Cyklokapron(PF) *126*
Cymbalta(LY) *1493*
CYPROTERONE
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 459
.GENITO URINARY SYSTEM AND SEX HORMONES 253
Cyproterone Sandoz (HX) *253*, *254*, *459*
Cystadane(RJ) *105*
DABIGATRAN 114, 115, 116
Dabigatran Sandoz (SZ) *115*, *116*
DABRAFENIB 381, 382
Daivobet (LO) *221*
Daktarin Tincture(JT) *219*
Daktarin(JT) *219*
Dalacin C(PF) *290*
Dantrium(PF) *1360*
DANTROLENE 1360
Daonil(SW) *75*
DAPAGLIFLOZIN 96, 97, 98, 99
DAPAGLIFLOZIN + METFORMIN 78, 79
Dapa-Tabs(AF) *144*
DAPSONE
.ANTIINFECTIVES FOR SYSTEMIC USE 301
.DERMATOLOGICALS 235
DARATUMUMAB 428, 429, 430
DAROLUTAMIDE 459, 460
Darzalex SC(JC) *429*, *430*, *431*
DASATINIB 324, 325, 327, 328, 330, 331, 333
Dasatinib ARX(XT) *325*, *326*, *327*, *328*, *329*, *330*, *331*, *333*, *335*
Dasatinib Dr.Reddy's (RI) *325*, *326*, *327*, *328*, *329*, *330*, *331*, *333*, *335*
Dasatinib SUN(RA). *325*, *326*, *327*, *328*, *330*, *331*, *333*, *335*
DASATINIB-TEVA (TB). *325*, *326*, *327*, *328*, *330*, *331*, *333*, *335*
DBL Cefotaxime(PF) *285*
DBL Heparin Sodium(PF) *111*
DBL Methotrexate(PF) *315*
DBL Promethazine Hydrochloride(PF)

.Prescriber Bag *29*
DBL Promethazine Hydrochloride(PF)
.ALIMENTARY TRACT AND METABOLISM *57*
DBL Promethazine Hydrochloride(PF)
.RESPIRATORY SYSTEM..... *1540*
Debrisoft Lolly(LC) *1700*
Debrisoft(LC) *1700*
DECITABINE + CEDAZURIDINE 317, 318, 319
DEGARELIX 465
DENOSUMAB..... 1370, 1371
Denpax(AF) *1405*, *1407*, *1408*, *1410*, *1411*, *1636*, *1637*, *1638*
Depo-Medrol(PF) *264*
Depo-Nisolone (FZ) *264*
Depo-Provera(PF) *240*
Deralin 10(AF) *149*
Deralin 40(AF) *149*
Dermatane (ZS) *232*
Dermatane(ZS) *232*
Desfax (AF)..... *1492*, *1493*
DESMOPRESSIN..... 257, 258, 259
Desmopressin Nasal Spray USP (Apotex)(DZ) *257*, *260*
DESVEN(RW)..... *1492*, *1493*
DESVENLAFAXINE..... 1492
Desvenlafaxine GH XR (GQ) *1492*, *1493*
Desvenlafaxine Sandoz (SZ) *1492*, *1493*
DEUCRAVACITINIB 1248
DEXAMETHASONE
.SENSORY ORGANS 1542, 1543, 1545
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS 262
DEXAMFETAMINE..... 1497
Dexmethsone(AS) *262*
DEXTRAN-70 + HYPROMELLOSE..... 1570
Diabex 1000(AL)..... *74*, *75*
Diabex 850(AL)..... *74*, *75*
Diabex XR 1000(AL)..... *74*, *75*
Diabex XR 500(AL)..... *74*, *75*
Diabex(AL)..... *74*, *75*
Diacomit(EU) *1453*
Diaformin 1000(AF) *74*
Diaformin 850(AF) *74*, *75*
Diaformin XR 1000(AF)..... *74*, *75*
Diaformin(AF) *74*, *75*
Dialamine(SB)..... *1613*
Diamicron 60mg MR(SE)..... *75*, *76*
Diamox(RW) *1547*
Diastix(DX)..... *1582*
DIAZEPAM 1482, 1483, 1642
Diazepam Elixir(ON) *1482*
Dibenyline(GH)
.CARDIOVASCULAR SYSTEM *149*
.GENITO URINARY SYSTEM AND SEX HORMONES *255*
Dicarz (AF)..... *153*, *154*
DICLOFENAC
.MUSCULO-SKELETAL SYSTEM 1353
.Repatriation Pharmaceutical Benefits Scheme 1663
Diclofenac Sandoz(SZ)..... *1353*, *1354*
DICLOXACILLIN..... 278
Dicloxacillin Mylan 250(AL)..... *278*
Dicloxacillin Mylan 500(AL)..... *278*
DICLOXACILLIN VIATRIS 250 (MQ)..... *278*
DICLOXACILLIN VIATRIS 500 (MQ)..... *278*
Difflam(IL) *36*, *1622*
Diflucan(PF)..... *297*, *298*
DIGOXIN..... 130
Dilantin Infatabs(UJ) *1432*
Dilantin Sodium(UJ)..... *1432*
Dilantin(UJ)..... *1432*
Dilart HCT 160/12.5 (AF).....*178*, *179*
Dilart HCT 160/25 (AF).....*178*, *179*
Dilart HCT 320/12.5 (AF).....*179*
Dilart HCT 320/25 (AF).....*179*
Dilart HCT 80/12.5 (AF).....*178*, *179*
Dilart(AF) *173*, *174*
Dilatrend 12.5(PB).....*153*, *154*
Dilatrend 25(PB).....*154*
Dilatrend 6.25(PB).....*154*
Dilaudid(MF).....*1377*, *1378*, *1379*, *1380*, *1625*
Dilaudid-HP(MF).....*1379*, *1625*
DILTIAZEM.....157
Diltiazem Sandoz CD(SZ) *157*
DIMETHYL FUMARATE.....1349
Dimethyl Fumarate MSN (LR) *1349*, *1350*
Dimethyl Fumarate Sandoz(SZ) *1349*, *1350*
Diovan (NV).....*173*, *174*
Dipentum(IX) *70*
DIPHENOXYLATE + ATROPINE SULFATE.....62
Diphereline(IS) *455*
DIPHTHERIA + TETANUS VACCINE 26, 313
Diprosone(AF) *223*, *224*
DIROXIMEL FUMARATE.....1350
DISOPYRAMIDE.....130
Distaph 250(AF) *278*
Distaph 500(AF) *278*
Dithiazide(FF).....*143*
Ditropan(SW).....*254*
Dizole 100(AF) *297*
Dizole 200(AF) *297*
Dizole 50(AF) *297*
DOCUSATE
.Repatriation Pharmaceutical Benefits Scheme.....1653, 1677
DOCUSATE + SENNOSIDE B 1654
Dolapril 0.5(RW).....*164*
Dolapril 1(RW).....*164*
Dolapril 2(RW).....*164*
Dolapril 4(RW).....*164*
DOMPERIDONE 51
DONEPEZIL 1502
Donepezil GH(HQ) *1502*, *1503*
Donepezil Sandoz (SZ) *1502*, *1503*
Doryx(YN).....*272*, *273*
DORZOLAMIDE 1548
DORZOLAMIDE + TIMOLOL 1549
Dostinex(PF) *238*, *239*
DOSULEPIN (DOTHIEPIN).....1487
Dosulepin Viatris 75(AL).....*1487*
Dosulepin Viatris(MQ) *1487*
Dothep 25(AF).....*1487*
Dothep 75(AF).....*1487*
Doubluts(GC) *256*
Doxsig (RW).....*272*, *273*
DOXYCYCLINE.....272, 273
Doxycycline Sandoz(HX).....*272*, *273*
Doxylin 100(AF).....*272*, *273*
Doxylin 50(AF).....*273*
D-Penamine(AL).....*1359*, *1360*
DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND.....1683
DRESSING ALGINATE CAVITY WOUND 1683
DRESSING ALGINATE SUPERFICIAL WOUND.....1683, 1684
DRESSING ALGINATE WITH MANUKA HONEY.....1684
DRESSING ALGINATE WITH SILVER CAVITY WOUND 1684
DRESSING ALGINATE WITH SILVER DEEP WOUND 1684
DRESSING CONTACT LAYER LIPIDOCOLLOID 1684

DRESSING CONTACT LAYER LIPIDOCOLLOID WITH SUCROSE OCTASULFATE 1684
DRESSING FILM 1685
DRESSING FILM ISLAND 1685
DRESSING FOAM HEAVY EXUDATE 1685, 1686
DRESSING FOAM LIPIDOCOLLOID WITH SILICONE HEAVY EXUDATE 1686
DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE 1686
DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE 1686
DRESSING FOAM MODERATE EXUDATE 1686
DRESSING FOAM WITH SILICONE 1687
DRESSING FOAM WITH SILICONE AND SILVER 1687
DRESSING FOAM WITH SILICONE HEAVY EXUDATE 1687, 1688
DRESSING FOAM WITH SILICONE LIGHT EXUDATE 1688
DRESSING FOAM WITH SILICONE MODERATE EXUDATE 1689
DRESSING FOAM WITH SILVER 1689
DRESSING GAUZE 1690
DRESSING GAUZE ABSORBENT 1690
DRESSING GAUZE PARAFFIN 1690
DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE 1690
DRESSING GELLING FIBRE 1690
DRESSING GELLING FIBRE LIPIDOCOLLOID 1691
DRESSING HYDROACTIVE DEBRIDEMENT 1691
DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM 1691, 1692
DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE 1692
DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE 1692
DRESSING HYDROCOLLOID CAVITY WOUND 1692
DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE 1692, 1693
DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE 1693, 1694
DRESSING HYDROFIBRE ALTERNATE TO ALGINATES 1694
DRESSING HYDROFIBRE WITH SILVER 1694
DRESSING HYDROGEL 1695
DRESSING HYDROGEL AMORPHOUS 1695
DRESSING HYDROGEL FOAM 1696
DRESSING HYDROGEL RIBBON 1696
DRESSING HYDROGEL SHEET 1696
DRESSING HYDROPHOBIC 1696
DRESSING LIPIDOCOLLOID MODERATE EXUDATE 1696
DRESSING NON ADHERENT 1697
DRESSING NON-ADHERENT ABSORBENT 1697, 1698
DRESSING NON-ADHERENT WITH SILICONE 1698
DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE 1698
DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE 1699
DRESSING TULLE NON-ADHERENT PRIMARY WOUND CONTACT LAYER PARAFFIN 1699
DRESSING WITH SILVER 1699
Drixine(BN) *1675*
DRY PSYLLIUM HUSK 1654
DULAGLUTIDE 95
Dulcolax(VZ) *60*, *1653*
Duloxecor (CR) *1493*
DULOXETINE 1493
Duloxetine Sandoz 30 (SZ) *1493*
Duloxetine Sandoz 60 (SZ) *1493*
Duloxetine Sandoz(HX) *1493*
Duocal(SB) *1618*
DuoCover(AV) *112*, *113*
Duodart 500ug/400ug(GK) *256*, *1667*
DuoDERM CGF 187660(CC) *1693*
DuoDERM CGF 187662(CC) *1693*
DuoDERM Extra Thin 187955(CC) *1693*
DuoDERM Gel 187990(CC) *1695*
DuoDERM Gel H7987(CC) *1695*
DuoDERM Paste 187930(CC) *1692*
Duodopa(VE) *1459*
Duofilm Solution(GK) *1663*
DuoPlidogrel (GZ) *112*, *113*
DuoResp Spiromax (EV) *1520*, *1522*, *1523*, *1525*
Duotrav(NV) *1552*
DUPILUMAB
.DERMATOLOGICALS 233
Dupixent(SW)
.DERMATOLOGICALS *235*
Durafiber 66800560(SN) *1690*
Durafiber 66800561(SN) *1691*
Durafiber 66800563(SN) *1691*
Duride (AF) *133*, *134*
Durogesic 100 (JC) *1412*, *1637*
Durogesic 12 (JC) *1405*, *1638*
Durogesic 25 (JC) *1407*, *1638*
Durogesic 50 (JC) *1409*, *1636*
Durogesic 75 (JC) *1410*, *1636*
DUTASTERIDE 256, 1668
DUTASTERIDE + TAMSULOSIN 255, 256, 1667
DYTREX 30(RW) *1493*
DYTREX 60(RW) *1493*
EAA Supplement(VF) *1613*
Ear Clear for Ear Wax Removal(KY) *1677*
Easiphen(SB) *1608*
Ebixa (LU) *1507*
Edronax(PF) *1494*
Efexor-XR(UJ) *1494*, *1495*
Efudix(IL) *1670*
Egoderm Cream(EO) *1663*
Egoderm Ointment(EO) *1663*
Egopsoryl-TA(EO) *1661*
Elastoplast 2225(BE) *1680*
Elastoplast 2226(BE) *1680*
Elastoplast 2227(BE) *1680*
Elaxine SR 150(RW) *1494*
Elaxine SR 37.5 (RW) *1494*
Elaxine SR 75(RW) *1495*
Eldepryl(OX) *1465*
Eleanor 150/30 ED(XT) *240*
EleCare LCP(AB) *1586*, *1587*
EleCare(AB) *1583*, *1584*, *1585*
ELETRIPTAN 1426
Eleuphrat(AL) *222*, *223*, *224*
Eleva 100 (AF) *1491*
Eleva 50 (AF) *1491*
Elidel(GO) *235*
Eligard 1 month(MF) *453*
Eligard 3 month(MF) *453*
Eligard 4 month(MF) *453*
Eligard 6 month(MF) *453*, *454*
Eliquis(BQ) *117*, *118*, *119*, *120*
Elocon Alcohol Free(AL) *229*, *230*, *1662*
Elocon(AL) *229*, *230*, *231*, *1662*
Eltroxin(LT) *266*, *267*, *268*
Emend IV(MK) *56*
EMEXLON (RW) *51*, *1622*
Emgality(LY) *1431*
EMPAGLIFLOZIN 99, 100, 101, 102

EMPAGLIFLOZIN + LINAGLIPTIN 79, 80
EMPAGLIFLOZIN + METFORMIN 80, 81
E-Mycin 200(AF) *289*
E-Mycin 400(AF) *289*
ENALAPRIL 158
ENALAPRIL + HYDROCHLOROTHIAZIDE 164, 165
Enalapril generichealth(GQ) *158*
Enalapril Sandoz (SZ) *158*
Enalapril Sandoz(SZ) *158*
Enalapril/HCT Sandoz(SZ) *164*, *165*
Enbrel (PF) *860*, *862*, *879*, *880*, *882*, *894*, *904*, *914*, *917*, *934*, *952*, *957*, *977*
Enbrel(PF) *855*, *856*, *859*, *867*, *874*, *876*, *878*, *884*, *889*, *892*, *897*, *902*, *908*, *911*, *929*, *939*, *943*, *948*, *962*, *970*
ENCORAFENIB 382, 383
Endep 10(AF) *1486*
Endep 25(AF) *1486*
Endep 50(AF) *1486*
ENDONE(AF) *1397*, *1398*, *1401*
Energivit(SB) *1612*
Enerzair Breezhaler(NV) *1532*
Enidin(VB) *1546*
Enlafax-XR (AF) *1494*, *1495*
ENOXAPARIN SODIUM 110, 111
Enstilar(LO) *221*
ENTACAPONE 1465
Entocort(EU) *63*
ENTRECTINIB 410
Entresto(NV) *185*, *186*
ENTRIP(RW) *1486*
Entyvio(TK) *1338*, *1340*, *1341*, *1342*, *1343*, *1345*
ENZALUTAMIDE 460, 461
Epclusa(GI) *312*
Epiduo(GA) *231*, *232*
Epidyolex(EU) *1440*, *1441*
Epilim EC(SW) *1437*, *1438*
Epilim Liquid(SW) *1437*, *1438*
Epilim Syrup(SW) *1437*, *1438*
Epilim(SW) *1437*, *1438*
EpiPen Jr.(AL)
.CARDIOVASCULAR SYSTEM *132*
.RESPIRATORY SYSTEM *1538*
EpiPen(AL)
.CARDIOVASCULAR SYSTEM *132*
.RESPIRATORY SYSTEM *1538*
Epiramax 100 (RW) *1456*
Epiramax 200 (RW) *1454*, *1455*
Epiramax 25 (RW) *1456*
Epiramax 50 (RW) *1456*
EPLERENONE 145, 146
EPROSARTAN 170, 171
EPROSARTAN + HYDROCHLOROTHIAZIDE 175
EPTINEZUMAB 1428, 1429
Erivedge(RO) *437*
ERLOTINIB 376, 377
Erlotinib APOTEX(TX) *376*, *377*
Erlotinib Sandoz (SZ) *376*, *377*
Erlyand(JC) *458*
ERYTHROMYCIN 289
ERYTHROMYCIN ETHYLSUCCINATE 289
ESCITALOPRAM 1488, 1489
Escitalopram GH (HQ) *1488*, *1489*
Escitalopram Sandoz(HX) *1488*, *1489*
Esipram (CF) *1488*, *1489*
Eskazole(AS) *1515*
ESOMEPRAZOLE 37, 38, 39, 40
ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN 50
Esomeprazole GH (GQ) *37*, *38*, *39*, *40*
Esomeprazole GxP(AF) *37*, *38*, *39*, *40*
Esomeprazole Mylan (AL) *37*, *38*, *39*, *40*
Esomeprazole RBX(RA) *37*, *38*, *39*, *40*
ESOMEPRAZOLE SANDOZ Hp7(SZ) *50*
Esomeprazole Viatris (MQ) *37*, *38*, *39*, *40*
Esopreze(BG) *37*, *38*, *39*, *40*
ESPLER (RW) *145*, *146*
Essential Amino Acid Mix(SB) *1613*
ESSENTIAL AMINO ACIDS FORMULA 1613
ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C 1613
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS 1613
Essential Care Jr(QH) *1605*, *1606*
Estalis continuous 50/140(SZ) *249*
Estalis continuous 50/250(SZ) *249*
Estalis sequi 50/140(SZ) *250*
Estalis sequi 50/250(SZ) *250*
Estraderm MX 100(JU) *246*
Estraderm MX 25(JU) *246*
Estraderm MX 50(JU) *246*
ESTRADIOL 245, 246
ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE 249
ESTRADIOL + NORETHISTERONE ACETATE 249
Estradiol Transdermal System (Sandoz, USA)(HX) *245*, *246*
Estradot 100 (SZ) *246*
Estradot 25(SZ) *246*
Estradot 37.5 (SZ) *245*
Estradot 50(SZ) *246*
Estradot 75 (SZ) *245*
ESTRIOL 246, 247
Estro-Pess(AS) *245*, *246*
ETANERCEPT 851, 853, 855, 856, 859, 860, 862, 864, 867, 869, 871, 874, 876, 878, 880, 882, 885, 889, 892, 894, 897, 902, 904, 908, 911, 914, 917, 922, 925, 929, 934, 939, 943, 948, 952, 957, 962, 970
ETHOSUXIMIDE 1433
Ethosuximide Essential Generics (UK)(IX) *1433*
ETONOGESTREL 240
ETOPOSIDE 321
Eucerin(BE) *1660*
Eutroxsig (LN) *267*, *268*
Evelyn 150/30 ED (GQ) *240*
Evenity(AN) *1373*
Everocan (CR) *1345*, *1346*
EVEROLIMUS
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 395, 396, 397, 1345, 1346
Evista(LY) *1372*
Evocair MDI(AF) *1527*, *1528*
EVOLOCUMAB 195, 196, 199
Evolve Carmellose(CX) *1568*
Evolve Hypromellose(CX) *1571*
Exarane (JU) *111*
Exarane Forte (JU) *111*
Exarane Forte(JU) *110*
Exelon Patch 10(NV) *1505*, *1506*
Exelon Patch 15(NV) *1505*, *1506*
Exelon Patch 5(NV) *1505*, *1506*
Exelon(NV) *1505*, *1506*
EXEMESTANE 462, 463
Exemestane GH (GQ) *462*, *463*
Exemestane Sandoz(SZ) *462*, *463*
Exforge 10/160(NV) *180*
Exforge 10/320(NV) *180*
Exforge 5/160(NV) *180*
Exforge 5/320(NV) *180*
Exforge 5/80(NV) *180*
Exforge HCT 10/160/12.5(NV) *183*
Exforge HCT 10/160/25(NV) *183*
Exforge HCT 10/320/25(NV) *183*

Exforge HCT 5/160/12.5(NV) *183*
Exforge HCT 5/160/25(NV) *183*, *184*
Extencilline Benzathine Benzylpenicillin (France)(YO) ... *26*, *276*
Extine 20 (RW) *1491*
Exufiber 709900(MH) *1690*
Exufiber 709901(MH) *1690*
Exufiber 709903(MH) *1690*
Exufiber 709908(MH) *1690*
Exufiber 709909(MH) *1690*
Eylea(BN) *1553*, *1554*, *1555*, *1556*, *1557*
Ezalo Composite Pack 10mg+10mg(AF) *208*, *210*
Ezalo Composite Pack 10mg+20mg(AF) *208*, *210*
Ezalo Composite Pack 10mg+40mg(AF) *208*, *210*
Ezalo Composite Pack 10mg+5mg(AF) *209*, *211*
EZEMICHOL (RW) *201*, *202*
Ezetast(XT).....*211*, *212*, *213*, *214*
EZETIMIBE..... 199, 201
EZETIMIBE (&) ROSUVASTATIN 208, 209, 210
EZETIMIBE + ATORVASTATIN 211, 212, 213, 214
EZETIMIBE + SIMVASTATIN.....214, 215, 216, 217
Ezetimibe GH(GQ)..... *201*, *202*
Ezetimibe Sandoz (SZ) *201*, *202*
Ezetimibe/Atorvastatin GH 10/10 (GQ) *212*, *214*
Ezetimibe/Atorvastatin GH 10/20 (GQ) *211*, *214*
Ezetimibe/Atorvastatin GH 10/40 (GQ) *211*, *213*
Ezetimibe/Atorvastatin GH 10/80 (GQ) *211*, *213*
EZETIMIBE/SIMVASTATIN SANDOZ (SZ) .. *215*, *216*, *217*, *218*
EZETORIN(RW) *215*, *216*, *217*, *218*
Ezetrol(AL)..... *201*, *202*
Ezovir (AF)..... *304*, *305*
EzSimva GH 10/10 (GQ) *216*, *217*
EzSimva GH 10/20 (GQ) *216*, *217*
EzSimva GH 10/40 (GQ) *215*, *218*
EzSimva GH 10/80 (GQ) *215*, *217*
FAMCICLOVIR 303, 304
FAMOTIDINE..... 36
Famvir (IX) *303*, *304*
Famvir(IX) *304*, *305*
Fareston(OX) *457*
FARICIMAB 1558, 1559, 1560
Faverin 100 (RW) *1490*
Faverin 50 (RW) *1490*
Favic 125(RW)..... *304*
Favic 250 (RW)..... *304*
Favic 250(RW)..... *303*
Favic 500 (RW)..... *305*
Favic 500(RW)..... *304*
Febridol (XT).....*1424*, *1425*, *1673*
FEBUXOSTAT..... 1361
Feldene-D(PF)..... *1356*
Felodil XR 10(RW)..... *155*, *156*
Felodil XR 5(RW)..... *156*
FELODIPINE 155, 156
Felodur ER 10 mg (TX)..... *155*, *156*
Felodur ER 2.5 mg(TX)..... *155*, *156*
Felodur ER 5 mg (TX)..... *156*
Femara 2.5 mg(NV) *463*, *464*
FEMIN(XT)..... *1358*
Femme-Tab ED 20/100(AE) *240*
Femme-Tab ED 30/150(AE) *240*
Femolet (AF)..... *463*, *464*
Femoston 1/10(GO)..... *249*
Femoston 2/10(GO)..... *249*
Fenac EC (AL) *1353*, *1354*
Fendex ER (AF)..... *155*, *156*
Fendex ER(AF)..... *155*, *156*
Fenocol (XT)..... *191*
FENOFIBRATE..... 191
Fenofibrate Cipla (LR) *191*
Fenofibrate Cipla(LR) *191*
FENOFIBRATE RBX (RA).....*191*
FENOFIBRATE RBX(RA).....*191*
Fenofibrate Sandoz(SZ) *191*
Fenofibrate Viatris (AL).....*191*
Fenpatch 100(RW) *1412*, *1637*
Fenpatch 12(RW) *1405*, *1638*
Fenpatch 25(RW) *1407*, *1638*
Fenpatch 50(RW) *1408*, *1636*
Fenpatch 75(RW) *1410*, *1636*
FENTANYL..... 1404, 1406, 1407, 1409, 1410, 1632, 1633, 1634, 1635, 1636, 1637, 1638
Fentanyl Sandoz(SZ). *1405*, *1407*, *1409*, *1410*, *1412*, *1636*, *1637*, *1638*
Fentora(TB) *1633*, *1635*
Ferinject(CS) *126*
FERRIC CARBOXYMALTOSE 126
FERRIC DERISOMALTOSE 126
Ferro-f-tab(AE) *127*, *1658*
Ferro-Liquid(AE).....*126*
Ferrosig(SI) *126*
Ferro-tab(AE) *126*, *1658*
FERROUS FUMARATE 126, 1658
FERROUS FUMARATE + FOLIC ACID 127, 1658
FERROUS SULFATE.....126
FEXOFENADINE.....1676
Fiasp Penfill(NO).....*71*
Fibsol 10 (RW) *159*
Fibsol 20 (RW) *159*
Fibsol 5 (RW) *159*
Finasta (SZ).....*1669*
FINASTERIDE.....1669
Finasteride GH 5(GQ) *1669*
Finasteride Mylan 5 (AF) *1669*
Finasteride-GA 5(GN).....*1669*
FINERENONE.....146
FINGOLIMOD.....1232, 1233
Fingolimod Sandoz (SZ).....*1233*
Fingolimod SUN(RA).....*1233*
Fingolimod-Teva (TB).....*1233*
FINGOLIS(LR).....*1233*
Finide(AL).....*1669*
Finnacar(RW).....*1669*
Finpro(RZ).....*1669*
Firmagon 120mg(FP) *465*
Firmagon 80mg(FP) *465*
Fixta 60(ZS).....*1372*
Flagyl S(SW) *295*, *296*
Flagyl(SW).....*295*, *296*
Flamazine(SN) *222*
FLECAINIDE 130
Flecainide Sandoz (SZ).....*131*
Flecatab(AF).....*131*
Flixotide Accuhaler(GK).....*1534*
Flixotide Junior Accuhaler(GK).....*1534*
Flixotide Junior(GK).....*1535*
Flixotide(GK) *1534*
Flomaxtra (LS).....*1668*
Flopen Viatris (MQ) *279*, *280*
Flopen(AL).....*279*, *280*
Florinef(AS) *260*
Flosix(AF).....*1668*
Fluanxol Concentrated Depot(LU).....*1468*
Fluanxol Depot(LU) *1468*
Flucil(AS).....*279*
Flucil(LN).....*279*
FLUCLOXACILLIN 278, 279
FLUCONAZOLE.....296, 297
Fluconazole APOTEX (GX).....*297*

Fluconazole Sandoz (SZ) *297*
Fluconazole Sandoz(SZ) *297*
Fludara(GZ) *315*
FLUDARABINE 315
FLUDROCORTISONE 260
FLUDROCORTISONE MEDSURGE (DZ) *260*
FLUNITRAZEPAM 1674
FLUOROMETHOLONE 1545
FLUOROURACIL 1670
Fluorouracil Viatris (AF) *1670*
FLUOTEX (RF) *1490*
FLUOXETINE 1490
Fluoxetine APOTEX(TY) *1490*
Fluoxetine Capsules 10 mg (Medreich, UK)(LM) *1490*
Fluoxetine generichealth (GQ) *1490*
Fluoxetine Sandoz(SZ) *1490*
FLUPENTIXOL DECANOATE 1467
FLUTAMIDE 461
Flutamin(AF) *461*
Fluticasone + Salmeterol Cipla 125/25 (LR) *1527*
Fluticasone + Salmeterol Cipla 250/25 (LR) *1528*
Fluticasone Cipla Inhaler (LR) *1534*
FLUTICASONE FUROATE 1534
FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL 1531
FLUTICASONE FUROATE + VILANTEROL 1525, 1526
FLUTICASONE PROPIONATE 1534, 1535
FLUTICASONE PROPIONATE + FORMOTEROL 1526
FLUTICASONE PROPIONATE + SALMETEROL 1526, 1527, 1528
Fluticasone Salmeterol Ciphaler 250/50(LR) *1527*
Fluticasone Salmeterol Ciphaler 500/50(LR) *1528*
flutiform 125/5(MF) *1526*
flutiform 250/10(MF) *1526*
flutiform 50/5(MF) *1526*
FLUVASTATIN 188
FLUVOXAMINE 1490
Fluzole 200 (RW) *297*
FML Liquifilm(VE) *1545*
FOLIC ACID 127, 128, 1659
FOLINIC ACID 1580
FOLLITROPIN ALFA 250
FOLLITROPIN BETA 251
Foltabs 500(PP) *127*, *1659*
Fonat(AL) *1362*, *1363*
FONDAPARINUX 125
Foradile(SZ) *1517*
Formet 1000 (RW) *74*
FORMET 500 (RF) *74*, *75*
FORMET 850 (RF) *74*, *75*
FORMOTEROL 1517
Forxiga(AP) *97*, *98*, *99*
Fosamax Plus 70 mg/140 mcg(MQ) *1367*, *1368*, *1672*
Fosamax Plus(MQ) *1368*, *1369*, *1672*
FOSAPREPITANT 55
FOSAPREPITANT MEDSURGE(DZ) *56*
FOSAPREPITANT MSN (RQ) *56*
FOSAPREPITANT-AFT (AE) *56*
Fosetic 20/12.5(ZP) *165*
FOSINOPRIL 159
FOSINOPRIL + HYDROCHLOROTHIAZIDE 165
FOSNETUPITANT + PALONOSETRON 51
Fosrenol(TK) *1577*
Fostair 200/6(EU) *1520*
Fostair(EU) *1519*
FRAMYCETIN SULFATE 1575
FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE 1575
FREMANEZUMAB 1429, 1430
FruitiVits(VF) *1619*
Frusax (ZS) *144*, *145*
Frusemix(TY) *144*, *145*
Frusemix-M(TY) *27*, *145*
Fucidin(LO) *295*
FULVESTRANT 455
FULVESTRANT ACCORD(OC) *456*
FULVESTRANT EVER PHARMA (IT) *456*
Fulvestrant Sandoz(SZ) *456*
Fungilin(AS) *36*
FUROSEMIDE 27, 144, 145
FUSIDATE 295
Fybogel(RC) *1654*
Fycompa(EI) *1450*, *1451*, *1452*, *1453*
Fynod (AF) *1233*
Fyzant (JU) *128*
GA gel(VF) *1607*
GA1 Anamix infant(SB) *1607*
GA1 Anamix Junior(NU) *1606*
Gabacor (CR) *1441*, *1673*
GABAPENTIN
.NERVOUS SYSTEM 1441
.Repatriation Pharmaceutical Benefits Scheme 1673
Gabapentin APOTEX(TY)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Gabapentin APOTEX(TY)
.NERVOUS SYSTEM *1441*
Gabapentin generichealth(HQ)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Gabapentin generichealth(HQ)
.NERVOUS SYSTEM *1441*
Gabapentin Sandoz (SZ)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Gabapentin Sandoz (SZ)
.NERVOUS SYSTEM *1441*
Gabitril(TB) *1436*, *1437*
GALANTAMINE 1503, 1504
Galantyl (AF) *1504*
GALCANEZUMAB 1430, 1431
Galvumet 50/1000(NV) *87*, *88*
Galvumet 50/500(NV) *87*, *88*
Galvumet 50/850(NV) *87*, *88*
Galvus(NV) *94*, *95*
Gamine XR(RW) *1504*, *1505*
Ganfort 0.3/5(VE) *1550*
GANfort PF 0.3/5(VE) *1550*
GAPENTIN (RF) *1441*
GAPENTIN(RF) *1441*
Gastrex(CR) *63*, *1655*
Gastro-Stop (AS) *63*
GAUZE AND COTTON TISSUE COMBINE ROLL 1700
GEFITINIB 377, 378
GELATIN + PECTIN + CARMELLOSE SODIUM 1660
GEMFIBROZIL 191, 192
Genox 20(AF) *456*, *457*
GenRx Perindopril/ Indapamide 4/1.25 (GX) *166*
GenRx Tamoxifen (GX) *456*, *457*
GENTAMICIN 290
Genteal gel(AQ) *1572*
Genteal(AQ) *1571*, *1572*
Gilenya(NV) *1233*
Gilmat(CR) *336*, *337*, *338*, *339*, *340*, *341*, *342*, *343*, *346*, *347*, *348*, *349*, *350*, *351*, *352*, *353*, *354*, *355*, *356*, *357*
GILTERITINIB 411, 412
Giotrif(BY) *376*
Glatira (JU) *467*
GLATIRAMER ACETATE 467
GLATIRAMER ACETATE-TEVA(EV) *467*
GLECAPREVIR + PIBRENTASVIR 311
Gliadel(EI) *314*
GLIBENCLAMIDE 75

GLICLAZIDE 75, 76
Gliclazide Lupin MR (GQ) *75*, *76*
Gliclazide MR Viatris (AL) *75*
GLIMEPIRIDE 76
Glimepiride APOTEX (GX) *76*
Glimepiride Sandoz(SZ) *76*
GLIPIZIDE 76, 77
Glivec (NV) *336*, *337*, *338*, *339*, *340*, *341*, *342*, *343*, *346*, *347*, *348*, *349*, *350*, *351*, *352*, *353*, *354*, *355*, *356*, *357*
GlucaGen Hypokit(NO) *27*, *270*
GLUCAGON HYDROCHLORIDE 27, 270
Glucobete 1000(ZS) *74*
Glucobete 500(ZS) *74*, *75*
Glucobete 850(ZS) *74*, *75*
GLUCOSE AND KETONE INDICATOR URINE 1582
GLUCOSE INDICATOR URINE 1582
Glyade MR(AF) *75*
Glyade(AF) *75*, *76*
GLYBOSAY (RW) *88*
GLYBOSAY(RW) *88*
GLYCEROL
.Repatriation Pharmaceutical Benefits Scheme 1654, 1663
GLYCEROL + WHITE SOFT PARAFFIN 1660
GLYCERYL TRINITRATE..... 27, 132, 133
GLYCINE WITH CARBOHYDRATE 1613
Glycine500(VF) *1613*
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE..... 1613
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS 1614
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE 1615
GLYCOPYRRONIUM 1535
Glycosade(VF) *1597*
Glyxambi(BY) *80*
Goanna Heat Cream(GQ) *1671*
GOLIMUMAB.977, 978, 980, 982, 985, 987, 989, 990, 993, 997, 1001, 1006
Gonal-f Pen(SG) *251*
Gopten(GO) *164*
GOSERELIN 452
GOSERELIN (&) BICALUTAMIDE..... 452
GRANISETRON 51, 52
Granisetron Kabi (PK) *51*, *52*
Granisetron-AFT(AE) *51*, *52*
GRISEOFULVIN 220
Grisovin 500(AS) *220*
Grisovin(AS) *220*
GUANFACINE 141
GUSELKUMAB..... 1054, 1059
Gynotril(ZS) *463*, *464*
Hadlima (RF) .*481*, *482*, *486*, *489*, *490*, *492*, *494*, *495*, *498*, *500*, *502*, *504*, *506*, *507*, *509*, *511*, *512*, *516*, *520*, *522*, *524*, *527*, *535*, *537*, *538*, *540*, *544*, *547*, *549*, *551*, *553*, *564*, *567*, *573*, *576*, *579*, *582*, *585*, *588*, *590*, *593*, *596*, *600*, *613*, *621*, *626*, *664*, *672*, *675*, *678*, *689*, *693*, *696*, *702*, *707*, *711*, *742*, *747*, *751*, *756*, *760*, *764*, *770*, *775*, *813*, *820*
Haldol decanoate(JC) *1466*, *1467*
HALOPERIDOL 26, 1466, 1642
HALOPERIDOL DECANOATE 1466
Hamilton Skin Therapy Oil(KY) *1661*
Hamilton Skin Therapy Wash(KY) *1664*
Handy 36361414(BV) *1678*
Handy 71117-05(BV) *1690*
Handy 71117-06(BV) *1690*
Handygauze Cohesive 8631(BV) *1680*
Handygauze Cohesive 8633(BV) *1680*
Handygauze Cohesive 8635(BV) *1680*
HCU Anamix infant(SB) *1607*
HCU Anamix junior LQ(SB) *1603*
HCU Anamix Junior(NU) *1607*
HCU cooler 20(VF) *1607*
HCU Easy Tablet(OH) *1603*
HCU explore5(VF) *1611*
HCU express 15(VF) *1607*
HCU Lophlex LQ 20(SB) *1607*
HCU Lophlex(SB) *1607*
HEPARIN 111
Hequinel (RW) *1359*
Herceptin SC(RO) *431*, *432*
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE 1615, 1616
Hikma(LM) *1378*, *1381*, *1626*
Hiprex(IL) *296*
HONEY BEE VENOM 1575
HPMC PAA(IQ) *1572*
Humalog KwikPen(KP) *72*
Humalog Mix25 KwikPen(KP) *73*
Humalog Mix25(LY) *73*
Humalog Mix50 KwikPen(KP) *73*
Humalog Mix50(LY) *73*
Humalog U200 Kwikpen(LY) *72*
Humalog(LY) *72*
HUMAN CHORIONIC GONADOTROPHIN 252
Humira (VE)... *481*, *482*, *487*, *489*, *498*, *502*, *516*, *535*, *540*, *544*, *547*, *553*, *564*, *567*, *573*, *576*, *579*, *582*, *585*, *588*, *590*, *593*, *603*, *606*, *616*, *621*, *626*, *632*, *636*, *641*, *651*, *656*, *699*, *716*, *720*, *724*, *729*, *734*, *738*, *780*, *781*, *786*, *799*, *806*
Humira(VE).... *483*, *516*, *518*, *529*, *533*, *555*, *558*, *561*, *570*, *610*, *611*, *629*, *647*, *791*
Humulin 30/70(LY) *73*
Humulin NPH(LY) *72*
Humulin R (LY) *72*
HYALURONATE SODIUM 1570
Hycor(AS) *1545*
Hydopa (AF) *140*
Hydrea(LM) *448*
HYDROCHLOROTHIAZIDE 143
HydroClean Plus 609602(HR) *1691*
HydroClean Plus 609606(HR) *1691*
HydroClean Plus 609608(HR) *1691*
HydroClean Plus Cavity 609622(HR) *1691*
Hydrocoll 900744(HR) *1693*
Hydrocoll 900936(HR) *1694*
Hydrocoll Thin 900758(HR) *1693*
HYDROCORTISONE 262, 263
HYDROCORTISONE ACETATE
.ALIMENTARY TRACT AND METABOLISM 65
.DERMATOLOGICALS 222
.Repatriation Pharmaceutical Benefits Scheme 1662
.SENSORY ORGANS 1545
HYDROCORTISONE SODIUM SUCCINATE 27, 263
Hydrocortisone Viatris 20(AL) *263*
Hydrocortisone Viatris 4(AL) *263*
HYDROMORPHONE 1377, 1378, 1380, 1624, 1625
Hydromorphone hydrochloride oral solution, USP (Medsurge)(DZ) *1378*, *1381*, *1626*
HYDROMORPHONE JUNO(JU) *1379*, *1625*
HYDROMORPHONE JUNO-HP(JU) *1379*, *1625*
Hydromorphone-hameln (HW) *1379*, *1625*
Hydromorphone-hameln-HP (HW) *1379*, *1625*
Hydrosorb 900854(HR) *1696*
Hydrosorb Comfort 900723(HR) *1695*
Hydroxo-B12(AS) *127*

HYDROXOCOBALAMIN..... 127, 1658
HYDROXYCARBAMIDE (HYDROXYUREA)..... 448
HYDROXYCARBAMIDE MEDSURGE (DZ)..... 448
HYDROXYCHLOROQUINE 1359
Hydroxychloroquine GH(GQ)..... 1359
HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE..... 128
Hygroton 25(GH) 144
Hylo-Forte(AE)..... 1571
Hylo-Fresh(AE)..... 1571
Hymenoptera Honey Bee Venom(DE)..... 1575
Hymenoptera Paper Wasp Venom(DE)..... 1575
Hymenoptera Yellow Jacket Venom(DE)..... 1576
HYOSCINE BUTYLBROMIDE..... 27, 1622, 1653
HYOSCINE BUTYLBROMIDE MEDSURGE(DZ) . 27, 1622, 1653
HYOSCINE BUTYLBROMIDE SXP (XN) 27, 1622, 1653
HYOSCINE BUTYLBROMIDE-AFT (AE)..... 27, 1622, 1653
Hypnodorm(AF) 1674
HYPROMELLOSE 1571
HYPROMELLOSE + CARBOMER-980 1572
Hyrimoz(SZ)...481, 482, 486, 489, 490, 492, 494, 495, 498, 500, 502, 504, 506, 507, 509, 511, 512, 516, 520, 522, 525, 527, 535, 537, 538, 540, 544, 547, 549, 551, 553, 564, 567, 573, 576, 579, 582, 585, 588, 590, 593, 596, 600, 613, 621, 626, 664, 672, 675, 678, 689, 693, 696, 702, 707, 711, 742, 747, 751, 756, 760, 764, 770, 775, 813, 820
Hysone 20(AF)..... 263
Hysone 4(AF)..... 263
IBANDRONATE..... 1363
Ibavyr(IX) 312
Ibilex 125 (AF) 282
Ibilex 250 (AF) 282, 283
Ibilex 500 (AF) 282, 283
Ibrance(PF)..... 392
IBRUTINIB..... 405
IBUPROFEN..... 1356, 1624
ICATIBANT..... 128
Icatibant Lupin(GQ) 128
ICHTHAMMOL..... 1663
ICHTHAMMOL + ZINC OXIDE 1663
Iclusig(TK)..... 371, 372, 375
Idacio (PK).....481, 482, 486, 489, 490, 492, 494, 495, 498, 500, 502, 504, 506, 507, 509, 511, 512, 516, 520, 522, 525, 527, 535, 537, 538, 540, 544, 547, 549, 551, 553, 564, 567, 573, 576, 579, 582, 585, 588, 590, 593, 596, 600, 613, 621, 626, 664, 672, 675, 678, 689, 693, 696, 702, 707, 711, 742, 747, 751, 756, 760, 764, 770, 775, 813, 820
Idaprex 2 (SZ)..... 160, 161
Idaprex 4 (SZ)..... 160
Idaprex 8 (SZ)..... 160, 161
Idaprex Combi 4/1.25(SZ)..... 166
IDELALISIB..... 408
Ikervis(CS)..... 1570
Ikotab (AF)..... 134
Ilumya(RA)..... 1143, 1150
Imatab(JU).....344, 352, 358, 359, 360, 362
IMATINIB335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360
Imatinib GH(GQ)....336, 337, 339, 340, 341, 342, 343, 347, 348, 350, 351, 352, 355, 357
IMATINIB RBX(RA)336, 337, 338, 339, 340, 341, 342, 343, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357
Imatinib Sandoz (SZ).....336, 337, 338, 339, 340, 341, 342, 343, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357
Imatinib-APOTEX(TX) ...335, 336, 337, 338, 339, 340, 341, 342, 343, 345, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357
IMATINIB-DRLA (RZ) 335, 336, 337, 338, 339, 340, 341, 342, 343, 345, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357
Imatinib-Teva(TB)..336, 337, 338, 339, 340, 341, 342, 343, 346, 347, 348, 349, 350, 351, 352, 354, 355, 356, 357
Imazan (ZS)..... 1349
Imbruvica(JC) 405, 406
Imdur 120 mg(IX) 133, 134
Imdur Durule(IX)..... 133, 134
Imigran FDT(AS) 1428
IMIGRAN MIGRAINE (AS) 1428
Imigran(AS) 1428
Imigran(LN) 1428
IMIPRAMINE..... 1487
Imipramine (Leading)(QY) 1487
IMIQUIMOD..... 236, 1663, 1664
Imoclone (RW) 1674
Imovane(SW) 1674, 1675
Implanon NXT(OQ)..... 240
Imrest(AF) 1675
Imuran(AS) 1349
In a Wink Moisturising(IQ) 1571, 1572
Inadine(KI)..... 1700
INCLISIRAN 202, 203, 205
Incruse Ellipta(GK) 1537
INDACATEROL..... 1517
INDACATEROL + GLYCOPYRRONIUM 1531
INDACATEROL + GLYCOPYRRONIUM + MOMETASONE 1532
INDACATEROL + MOMETASONE 1528
INDAPAMIDE..... 144
Inderal(IX)..... 149
Indocid(AS)..... 1354, 1624
INDOMETACIN 1354, 1623
Indosyl Combi 4/1.25 (RW) 166
Indosyl Mono 2(RW)..... 160, 161
Indosyl Mono 4(RW)..... 160, 161
Indosyl Mono 8(RW)..... 160, 161
INFLIXIMAB 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1020, 1021, 1023, 1024, 1026, 1028, 1030, 1032, 1034, 1036, 1038, 1040, 1670
Inlyta(PF)..... 402, 403
iNova Pharmaceuticals (Australia) Pty Ltd(IL) 1513
Inpler(AF) 145, 146
Inqovi 35/100(OS) 317, 318, 319
Insig (RW) 144
Inspra (UJ)..... 145, 146
INSULIN ASPART..... 71
INSULIN ASPART + INSULIN ASPART PROTAMINE 72
INSULIN DEGLUDEC + INSULIN ASPART..... 73
INSULIN DETEMIR 73
INSULIN GLARGINE..... 73, 74
INSULIN GLULISINE..... 72
INSULIN ISOPHANE HUMAN..... 72
INSULIN LISPRO 72
INSULIN LISPRO + INSULIN LISPRO PROTAMINE..... 73
INSULIN NEUTRAL HUMAN 72
INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN..... 73
INTERFERON BETA-1B 465
Intrasite Gel 7313(SN)..... 1695
Intuniv(TK)..... 142
Invega Hafyera(JC) 1476
Invega Sustenna(JC)..... 1475
Invega Trinza(JC)..... 1475
Invega(JC)..... 1475
Iodosorb 66051330(SN) 1682

Iodosorb 66051340(SN) *1682*
Iodosorb 66051360(SN) *1682*
Iodosorb Ointment 66051230(SN) *1682*
Iodosorb Ointment 66051240(SN) *1682*
Iodosorb Powder 66051070(SN) *1682*
Ionil-T(GA) *1663*
I-Pantoprazole (CR) *46*, *47*, *48*
Ipratrin (AF) *1536*
Ipratrin Adult (AF) *1536*
IPRATROPIUM 1535
Iptam (AL) *1428*
IRBESARTAN 171, 172
IRBESARTAN + HYDROCHLOROTHIAZIDE 175, 176
Irbesartan GH (GQ) *171*, *172*
Irbesartan Sandoz(SZ) *171*, *172*
Irbesartan/HCT Sandoz(SZ) *175*, *176*
IRON POLYMALTOSE 126
IRON SUCROSE 127
Iscover(AV) *112*, *1658*
ISOBIDE MR(RF) *133*, *134*
Isoleucine 1000(VF) *1617*
Isoleucine 50(VF) *1617*
ISOLEUCINE WITH CARBOHYDRATE 1617
ISONIAZID 301
Isoptin 180 SR(GO) *157*
Isoptin SR(GO) *157*
Isoptin(GO) *157*
Isopto Carpine(NV) *1547*
Isordil Sublingual(RW) *133*
ISOSORBIDE DINITRATE 133
ISOSORBIDE MONONITRATE 133
ISOTRETINOIN 232
Isotretinoin GX(SZ) *232*
Isotretinoin Lupin (GQ) *232*
Itracap (AF) *298*
ITRACONAZOLE 298
ITRANOX(RW) *298*
IVABRADINE 136
IVERMECTIN 1516
IXEKIZUMAB 1067, 1069, 1072, 1076, 1082
Jakavi(NV) *400*, *401*, *402*
Janumet XR(XW) *86*, *87*
Janumet(XW) *85*, *86*
Januvia(XW) *93*, *94*
Jardiamet 12.5 mg/1000 mg(BY) *81*, *82*
Jardiamet 12.5 mg/500 mg(BY) *81*
Jardiamet 5 mg/1000 mg(BY) *81*
Jardiamet 5 mg/500 mg(BY) *81*
Jardiance(BY) *100*, *101*, *102*
Jelonet 7404(SN) *1690*
Jinarc(OS) *148*
JJ 12010(JJ) *1700*
Jorveza(FD) *64*, *65*
K.Yo(VF) *1615*
Kalixocin(AF) *288*
Kalma 0.25(AF) *1482*
Kalma 0.5 (AF) *1482*
Kalma 1 (AF) *1482*
Kaltostat 168117(CC) *1683*
Kaltostat 168210(CC) *1683*
Kaltostat 168212(CC) *1683*
Kapanol(YN) *1393*, *1629*, *1630*
Kaptan(ZS) *1471*, *1472*
Karlor CD(MQ) *285*
Karvea (SW) *171*, *172*
Karvezide 150/12.5 (SW) *176*
Karvezide 300/12.5 (SW) *176*
Karvezide 300/25 (SW) *176*
Keflex(AS) *282*, *283*
Keflor CD (AF) *285*
Keflor(AF) *284*, *285*
Kenacomb Otic(AS) *1575*
Kenacort-A10(AS) *265*, *266*
Keppra (UC) *1448*, *1449*, *1450*
Kerendia(BN) *146*
Kerron(ZS) *1449*, *1450*
Kesimpta(NV) *1337*
KetoCal 3
1(SB) *1616*
KetoCal 4
1 LQ(SB) *1615*
1(SB) *1616*
Keto-Diastix(DX) *1582*
KETOPROFEN 1356
KetoVie 3
1(QH) *1616*
KetoVie 4
1(QH) *1616*
KetoVie Peptide 4
1(QH) *1617*
Kevtam 1000(AF) *1448*, *1449*
Kevtam 250(AF) *1448*, *1449*
Kevtam 500(AF) *1449*
keyomega(VF) *1612*
Kindergen(SB) *1620*
Kinson (AF) *1458*
Kisqali(NV) *393*, *394*, *395*
Klacid(GO) *288*
Kombiglyze XR 2.5/1000(AP) *84*, *85*
Kombiglyze XR 5/1000(AP) *84*, *85*
Kombiglyze XR 5/500(AP) *84*, *85*
Konakion MM(PB) *29*
Kosteo (RW)
.ALIMENTARY TRACT AND METABOLISM *102*, *103*
.MUSCULO-SKELETAL SYSTEM *1370*
Kuvan(IO) *106*, *107*, *108*, *109*
Kyleena(SY) *236*
Kytril(IX) *51*, *52*
L.C.E. Sandoz (HX) *1460*
LABETALOL 154
Lacoress(LR) *1442*, *1443*, *1444*, *1445*
Lacosam (AF) *1442*, *1443*, *1444*, *1445*
Lacosam(AF) *1442*, *1443*, *1446*, *1447*
LACOSAMIDE 1441, 1442, 1443, 1444, 1445, 1446
Lacosamide ARX (XT) *1442*, *1443*, *1446*, *1447*
Lacosamide ARX(XT) *1442*, *1443*, *1444*, *1445*
Lacosamide Lupin (GQ) *1442*, *1443*, *1444*, *1445*
Lacosamide Lupin(GQ) *1442*, *1443*, *1446*, *1447*
Lacosamide Sandoz (SZ) *1442*, *1443*, *1446*, *1447*
Lacosamide Sandoz(SZ) *1442*, *1443*, *1444*, *1445*
Lagevrio(MK) *28*, *307*
Lamictal(AS) *1447*, *1448*
Lamisil (Novartis Pharmaceuticals Australia Pty Limited) (NV) *220*, *1660*
Lamisil DermGel(NP) *1660*
Lamisil(NP) *220*, *1660*
LAMITAN (RF) *1447*, *1448*
LAMOTRIGINE 1447
Lamotrigine GH(GQ) *1447*, *1448*
LANADELUMAB 128
Lanoxin(AS) *130*
Lanoxin-PG(AS) *130*
LANSOPRAZOLE 41, 42
Lansoprazole ODT GH (GQ) *41*, *42*, *43*
LANTHANUM 1576, 1577
Lanvis(AS) *315*
Lanzopran (RA) *41*, *42*, *43*
LAPATINIB 398
Largactil(IX) *26*, *1466*
LAROTRECTINIB 412

Lasix(SW) *27*, *144*, *145*
LATANOPROST 1550
LATANOPROST + TIMOLOL 1551
Latanoprost Sandoz (SZ) *1550*, *1551*
Latuda (SE) *1467*
Lavione(AF) *1467*
Lax-Tab(AE) *59*
Lecteva(TB) *1460*
LEFLUNOMIDE 1346, 1347, 1348
Leflunomide APOTEX (GX) *1347*, *1348*
Leflunomide APOTEX(GX) *1347*, *1348*
Leflunomide generichealth (HQ) *1347*, *1348*
Leflunomide generichealth(HQ) *1347*, *1348*
Leflunomide Sandoz (SZ) *1347*, *1348*
Leflunomide Sandoz(SZ) *1347*, *1348*
Lenest 30 ED (AF) *240*
Lengout (LN) *1362*
LENVATINIB 414, 415, 416
Lenvima(EI) *414*, *415*, *416*, *417*
Leqvio(NV) *202*, *205*, *208*
Lercan(RW) *156*
LERCANIDIPINE 156
LERCANIDIPINE + ENALAPRIL 166, 167
Lercanidipine APOTEX (GX) *156*
Lescol XL(NV) *188*
LETROZOLE 463
Letrozole APOTEX (GX) *463*, *464*
Letrozole GH(HQ) *463*, *464*
Letrozole Sandoz (SZ) *463*, *464*
Leucovorin Calcium (Hospira Pty Limited)(PF) *1580*
Leucovorin Calcium (Pfizer Australia Pty Ltd)(PF) *1580*
Leukeran(AS) *313*
Leukoflex 1124(BV) *1701*
Leukoplast 01071-00(BV) *1700*
Leukoplast 01072-00(BV) *1700*
Leukoplast 01073-00(BV) *1701*
Leukopor 2471(BV) *1701*
Leukopor 2472(BV) *1701*
Leukopor 2474(BV) *1701*
Leukosilk 1021(BV) *1701*
Leukosilk 1022(BV) *1701*
Leukosilk 1024(BV) *1701*
LEUPRORELIN 453, 454
LEUPRORELIN (&) BICALUTAMIDE 454
Levactam (ZS) *1448*, *1449*
Levemir FlexPen(NF) *73*
Levemir Penfill(NO) *73*
LEVETIRACETAM 1448, 1449, 1450
Levetiracetam GH(GQ) *1448*, *1449*, *1450*
Levetiracetam Mylan (AL) *1448*, *1449*
Levetiracetam SZ(SZ) *1448*, *1449*
Levetiracetam Viatris (MQ) *1448*, *1449*
Levetiracetam-AFT (AE) *1449*, *1450*
Levi 1000(RW) *1448*, *1449*
Levi 250(RW) *1449*
Levi 500 (RW) *1449*
Levlen ED(SY) *240*
LEVODOPA + BENSERAZIDE 1458
LEVODOPA + CARBIDOPA 1458, 1459
LEVODOPA + CARBIDOPA + ENTACAPONE 1459
LEVONORGESTREL
.GENITO URINARY SYSTEM AND SEX HORMONES 236, 240
LEVONORGESTREL + ETHINYLESTRADIOL
.GENITO URINARY SYSTEM AND SEX HORMONES 240
Levothox (AF) *267*, *268*
LEVOTHYROXINE 266, 267, 268
Levothyroxine Lup(GQ) *267*, *268*
Levothyroxine Sandoz (SZ) *267*, *268*
LEVOXINE(RA) *266*, *267*
Lexam 10(RW) *1488*, *1489*
Lexam 20(RW) *1488*, *1489*
Lexapro(LU) *1488*, *1489*, *1490*
Lexotan(PB) *1674*
LIDOCAINE
.CARDIOVASCULAR SYSTEM 130
.Prescriber Bag 27
.Repatriation Pharmaceutical Benefits Scheme 1661
LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM 1664
Lignocaine Injection (Pfizer)(WZ) *27*
LINAGLIPTIN 90, 91
LINAGLIPTIN + METFORMIN 82
Lincocin(PF) *290*
LINCOMYCIN 290
LINCOMYCIN SXP(XN) *290*
Link Medical Products Pty Ltd(LM)
.Prescriber Bag *26*
Link Medical Products Pty Ltd(LM)
.CARDIOVASCULAR SYSTEM *131*
Link Medical Products Pty Ltd(LM)
.CARDIOVASCULAR SYSTEM *131*
Link Medical Products Pty Ltd(LM)
.DERMATOLOGICALS *235*
Link Medical Products Pty Ltd(LM)
.DERMATOLOGICALS *236*
Link Medical Products Pty Ltd(LM)
.ANTIINFECTIVES FOR SYSTEMIC USE *302*
Link Medical Products Pty Ltd(LM)
.ANTIINFECTIVES FOR SYSTEMIC USE *302*
Link Medical Products Pty Ltd(LM)
.RESPIRATORY SYSTEM *1537*
Link Medical Products Pty Ltd(LM)
.RESPIRATORY SYSTEM *1538*
Lioresal 10(NV) *1360*
Lioresal 25(NV) *1360*
LIOTHYRONINE 268
Lipex 20(AL) *190*, *191*
Lipex 40(AL) *190*, *191*
Lipidil(GO) *191*
Lipigem (AF) *192*
Lipistart(VF) *1596*, *1597*
Lipitor (AS) *186*, *187*
Lipitor(AS) *187*
Lipostat 10 (RF) *188*
Lipostat 20(RF) *188*
Lipostat 40(RF) *188*
Lipostat 80 (RF) *188*
LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE 1572
Liquigen(SB) *1582*
LISDEXAMFETAMINE 1497
LISINOPRIL 159
Lisinopril generichealth(GQ) *159*
Lisinopril Sandoz (SZ) *159*
Lisinopril Sandoz(SZ) *159*
Lithicarb(AS) *1493*
LITHIUM CARBONATE 1493
Locasol(SB) *1600*
Loceryl(GA) *1659*
Lofenoxal(IL) *62*
Logem (AL) *1447*, *1448*
Logicin Rapid Relief(AS) *1675*
Logynon ED(SY) *240*
Lomotil(IM) *62*
Loniten(PF) *143*
Lonsurf 15/6.14(SE) *320*

Lonsurf 20/8.19(SE) *320*
LOPERAMIDE 62, 63, 1655
LORATADINE 1676
LORLATINIB 387
Lorstat 10(AF) *186*, *187*
Lorstat 20(AF) *187*
Lorstat 40(AF) *187*
Lorstat 80 (AF) *187*
Lorviqua(PF) *388*
Losec Tablets(PB) *43*, *44*, *45*
LoxaLate (AF) *1488*, *1489*
Lozanoc(YN) *299*
LPV (IL) *277*, *278*
LUBRICATING AGENT 1678
Lubri-Gel(PP) *1678*
Lucentis(NV) *1561*, *1562*, *1563*, *1564*, *1565*, *1566*
Lucrin Depot 3 Month PDS(VE) *453*
Lucrin Depot 4 Month PDS(VE) *453*
Lucrin Depot 6-Month(VE) *453*
Lucrin Depot 7.5mg PDS(VE) *453*
Lucrin Depot Paediatric 30 mg PDS(VE) *454*
Lumigan (VE) *1550*
Lumigan PF(VE) *1550*
Lumin 10(AF) *1493*
Lumin 20(AF) *1493*
Lunava 10 (RW) *1347*
Lunava 20(RW) *1347*, *1348*
LURASIDONE 1467
Lurasidone Lupin (GQ) *1467*
Lurasidone Sandoz(SZ) *1467*
LURASIDONE SUN (RA) *1467*
Luvox(GO) *1490*
Lyclear(ON) *1517*
Lynparza(AP) *444*, *445*, *446*, *447*, *448*
Lyrica(UJ) *1425*, *1426*
LYSINE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + FERRIC PYROPHOSPHATE 1656
Lyzalon (AF) *1425*, *1426*
MACROGOL-3350 ..... 60, 1622
MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE 60, 1623
Macrovic (RF) *61*, *1623*
Madopar 125(RO) *1458*
Madopar 62.5(RO) *1458*
Madopar HBS(RO) *1458*
Madopar Rapid 125(RO) *1458*
Madopar Rapid 62.5(RO) *1458*
Madopar(RO) *1458*
MagMin (PBS)(BB) *105*
Magmin(BB) *1657*
MAGNESIUM 105, 1657
Mag-Sup (PP) *105*
Mag-Sup(PP) *1657*
Malarone (GK) *1514*
Malean (RW) *158*
Malean(RW) *158*
Marevan (GT) *110*
Marevan(GT) *110*
MAVACAMTEN 136, 137, 138
Mavenclad(SG) *478*
Maviret(VE) *311*
Maxalt(AL) *1427*
Maxamox(SZ) *274*, *275*
Maxidex(NV) *1542*
Maxolon(IL) *51*, *1622*
Maxor (AF) *43*, *44*, *45*
Maxor EC Tabs (AF) *43*, *44*, *45*
Mayne Pharma Doxycycline(YT) *272*, *273*
Mayne Pharma Erythromycin(YT) *289*
Mayne Pharma Oxycodone IR(YN) *1397*, *1401*
Mayzent(NV) *1239*
MCT Oil(SB) *1582*
MEBENDAZOLE 1675
MEBEVERINE 1653
MEDICHOICE Ibuprofen 400 mg (NB) *1356*, *1624*
Medicianz Mupirocin Ointment(DZ) *1662*
Medipore 2961(MM) *1700*
MEDIUM CHAIN TRIGLYCERIDES 1582
MEDROXYPROGESTERONE
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 451
.GENITO URINARY SYSTEM AND SEX HORMONES 240, 247
MEDSURGE HYDROMORPHONE 2 mg/1 mL (DZ) ... *1379*, *1625*
MEDSURGE HYDROMORPHONE HP 10 mg/1 mL (DZ) *1379*, *1625*
MEFENAMIC ACID 1358
Mefix 310250(MH) *1700*
Megafol 0.5 (AF) *127*, *1659*
Megafol 5(AF) *128*, *1659*
Mekinist(NV) *389*, *390*
Mektovi(FB) *388*
MELATONIN 1485
Melgisorb Ag 256055(MH) *1684*
Melgisorb Ag 256105(MH) *1684*
Melgisorb Ag 256605(MH) *1684*
Melizide(AF) *77*
MELOBIC (RF) *1355*
MELOBIC(RF) *1355*
Melolin 36361357(SN) *1697*
Melolin 66974933(SN) *1697*
Meloxibell (GQ) *1355*
MELOXICAM 1354, 1355
Meloxicam Sandoz(SZ) *1355*
Meloxicam Viatris (AL) *1355*
MELPHALAN 313
MEMANTINE 1506, 1507
Memantine generichealth(GQ) *1507*
Memanxa (RW) *1507*
Mepilex 294100(MH) *1689*
Mepilex Ag(MH) *1687*
Mepilex Border Ag(MH) *1687*
Mepilex Border Flex 595211(MH) *1687*
Mepilex Border Flex 595311(MH) *1687*
Mepilex Border Flex 595611(MH) *1688*
Mepilex Border Flex Lite 581011(MH) *1689*
Mepilex Border Flex Lite 581100(MH) *1689*
Mepilex Border Flex Lite 581300(MH) *1689*
Mepilex Border Heel 282750(MH) *1688*
Mepilex Border Lite 281000(MH) *1688*
Mepilex Border Lite 281100(MH) *1688*
Mepilex Border Lite 281300(MH) *1688*
Mepilex Border Sacrum 282050(MH) *1688*
Mepilex Border Sacrum 282450(MH) *1688*
Mepilex Lite 284000(MH) *1688*
Mepilex Lite 284100(MH) *1688*
Mepilex XT 211015(MH) *1685*
Mepilex XT 211100(MH) *1685*
Mepilex XT 211400(MH) *1686*
Mepitac 298300(MH) *1701*
Mepitac 298400(MH) *1701*
Mepitel 290510(MH) *1697*
Mepitel 290710(MH) *1697*
Mepitel One 289100(MH) *1698*
Mepitel One 289500(MH) *1698*
MERCAPTOPURINE 315
MERCAPTOPURINE-LINK(LM) *315*
MESALAZINE 66, 67, 68, 69

Mesalazine 1.2 TAKEDA(NQ) ... *69*
MESALZ(RA) ... *69*
Mesasal(GO) ... *67*
MESNA ... 1580
Mesorb 677001(MH) ... *1697*
Mesorb 677401(MH) ... *1698*
Mesorb 677701(MH) ... *1698*
Mestinon Timespan(IL) ... *1508*
Mestinon(IL) ... *1508*
Metalyse(BY) ... *114*
Metamucil Natural Granular(PY) ... *1654*
Metamucil Orange Smooth(PY) ... *1654*
METEX XR (RF) ... *74*, *75*
Metex XR(RW) ... *74*, *75*
METFORMIN ... 74
Metformin GH (HQ) ... *74*, *75*
Metformin Sandoz (SZ) ... *74*, *75*
Metformin Sandoz(SZ) ... *74*, *75*
METHADONE
.NERVOUS SYSTEM ... 1412, 1413
.Palliative Care ... 1638, 1639, 1640
METHENAMINE HIPPURATE ... 296
Methoblastin(PF)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS ... *315*, *1350*, *1351*
Methopt(AF) ... *1571*, *1572*
METHOTREXATE
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS ... 315, 1350, 1351
METHOXYFLURANE ... 27
METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM EXTRACT ... 1671
METHYLDOPA ... 140
METHYLNALTREXONE ... 1623
METHYLPHENIDATE ... 1498, 1499, 1500
Methylphenidate XR ARX(XT) ... *1499*
METHYLPHENIDATE-TEVA XR (TB) ... *1499*
Methylpred(AL) ... *263*
METHYLPREDNISOLONE
.DERMATOLOGICALS ... 226, 227, 228
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS ... 263, 264
METOCLOPRAMIDE ... 28, 51, 1622
METOCLOPRAMIDE INJECTION BP(WZ) ... *28*, *51*, *1622*
Metoprolol Sandoz (SZ) ... *152*
METOPROLOL SUCCINATE ... 151
METOPROLOL TARTRATE ... 152
Metrogyl 200(AF) ... *295*
Metrogyl 400(AF) ... *296*
Metrol 100(RW) ... *152*
Metrol 50(RW) ... *152*
Metrol-XL 190(RW) ... *151*, *152*
Metrol-XL 23.75(RW) ... *151*
Metrol-XL 47.5(RW) ... *151*, *152*
Metrol-XL 95(RW) ... *151*, *152*
METRONIDAZOLE ... 295, 296
Mextra Superabsorbent 610000(MH) ... *1698*
Mextra Superabsorbent 610300(MH) ... *1697*
Mextra Superabsorbent 610500(MH) ... *1697*
Mezavant (TK) ... *69*
Miacalcic 100(EU) ... *271*
MIANSERIN ... 1493
Micardis Plus 40/12.5 mg(BY) ... *178*
Micardis Plus 80/12.5 mg(BY) ... *178*
Micardis Plus 80/25 mg(BY) ... *178*
Micardis(BY) ... *173*
Micolette(AE) ... *61*, *1623*, *1654*
MICONAZOLE ... 219
Microdacyn(TF) ... *1700*
Microgynon 50 ED(BN) ... *240*
Microlut 28(BN) ... *240*
Micronelle 30 ED(TX) ... *240*
MIDAZOLAM ... 28
MIFEPRISTONE (&) MISOPROSTOL ... 254
MILK POWDER SYNTHETIC LOW CALCIUM ... 1600
MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE ... 1617
Minax 100 (AF) ... *152*
Minax 50 (AF) ... *152*
Minax XL (AF) ... *151*, *152*
Minidiab (PF) ... *77*
Minipress (PF) ... *142*, *143*
Minirin Melt(FP) ... *258*, *259*
Minirin Nasal Spray(FP) ... *257*, *260*
Minirin(FP) ... *257*, *258*, *259*
Minitran 10(IL) ... *132*
Minitran 15(IL) ... *132*
Minitran 5(IL) ... *133*
MINOCYCLINE ... 274
Minomycin-50 (AS) ... *274*
MINOXIDIL ... 143
Mirena(BN) ... *236*
MIRTANZA (RF) ... *1494*
MIRTANZA ODT(RF) ... *1494*
MIRTAZAPINE ... 1493
Mirtazapine Sandoz(SZ) ... *1494*
Mistrom(ZS) ... *152*
Mixtard 30/70 InnoLet(NI) ... *73*
Mixtard 30/70 Penfill 3 mL (NO) ... *73*
Mizart (AF) ... *173*
Mizart HCT 40/12.5 mg (AF) ... *177*, *178*
Mizart HCT 80/12.5 mg (AF) ... *178*
Mizart HCT 80/25 mg (AF) ... *178*
MMA/PA Anamix infant(SB) ... *1608*
MMA/PA Anamix Junior(NU) ... *1608*
MMA/PA express 15(VF) ... *1608*
Mobic(BY) ... *1355*
MOCLOBEMIDE ... 1492
Moclobemide Sandoz(SZ) ... *1492*
Modafin (RW) ... *1502*
MODAFINIL ... 1501
Modafinil GH(GQ) ... *1502*
Modafinil Mylan (AF) ... *1502*
Modafinil Sandoz(SZ) ... *1502*
Modafinil Viatris (AL) ... *1502*
Modavigil(TB) ... *1502*
MODIFIED LONG CHAIN AMYLOPECTIN ... 1597
Moduretic(AS) ... *147*
Mogadon (IL) ... *1434*, *1484*, *1643*
Molaxole(GO) ... *61*, *1623*
MOLNUPIRAVIR ... 28, 305
Momasone Alcohol Free(AS) ... *229*, *230*
Momasone(AS) ... *229*, *230*
MOMETASONE ... 228, 229, 230, 231, 1662
Monace 10 (AF) ... *159*
Monace 20 (AF) ... *159*
Monodur 120 mg(IY) ... *133*, *134*
Monofer(FK) ... *126*
Monogen(SB) ... *1596*, *1597*
MONTELAIR 4(RF) ... *1539*
MONTELAIR 5(RF) ... *1540*
MONTELUKAST ... 1539
Montelukast APOTEX (GX) ... *1539*, *1540*
Montelukast Lupin(HQ) ... *1539*, *1540*
Montelukast Mylan (AF) ... *1539*, *1540*
Montelukast Sandoz 4(SZ) ... *1539*
Montelukast Sandoz 5(SZ) ... *1540*

MORPHINE28, 1381, 1382, 1383, 1385, 1386, 1387, 1389, 1390, 1391, 1393, 1395, 1626, 1627, 1628, 1629, 1630, 1672
Morphine Juno(JU) *28*, *1381*, *1382*, *1384*, *1385*, *1389*, *1627*, *1628*
MORPHINE MR APOTEX(TX) *1393*, *1630*
Morphine MR Mylan (AF)..... *1393*, *1630*
Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL(LM).....*1382*, *1387*, *1626*, *1627*
Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)(DZ)1382, *1387*, *1627*
MORPHINE SULFATE 10 mg/1 mL MEDSURGE(DZ)1382, *1389*, *1628*
MORPHINE SULFATE 15 mg/1 mL MEDSURGE(DZ)... *28*, *1381*, *1384*, *1627*
MORPHINE SULFATE 30 mg/1 mL MEDSURGE(DZ)... *28*, *1381*, *1384*, *1627*
Morphini HCl Streuli(DZ).....*1383*, *1396*, *1627*
Motilium (JT)..... *51*
Movalis 15 (RW) *1355*
Movalis 15(RW) *1355*
Movalis 7.5 (RW) *1355*
Movalis 7.5(RW) *1355*
Movapo Pen(TD) *1461*
Movapo PFS(TD)..... *1461*
Movapo(TD)..... *1460*
Movicol(NE) *61*, *1623*
Movox 100(AF) *1490*
Movox 50(AL) *1490*
Moxicam 15 (AF) *1355*
Moxicam 7.5 (AF) *1355*
Moxicam(AF) *1355*
MOXONIDINE..... 142
Moxonidine GH (GQ) *142*
Moxonidine GX(SZ) *142*
Moxonidine Viatris (AL)..... *142*
Moxotens(RF)..... *142*
MS Contin(MF) *1390*, *1393*, *1395*, *1630*, *1672*
MS Mono(MF).....*1393*, *1629*, *1630*
MS-2 Step(XH) *254*
MSUD amino5(VF) *1612*
MSUD Anamix infant(SB) *1610*
MSUD Anamix Junior LQ(SB)..... *1610*
MSUD Anamix Junior(SB) *1610*
MSUD cooler 15(VF) *1610*
MSUD cooler 20(VF) *1610*
MSUD Easy Tablet(OH)..... *1603*
MSUD explore5(VF) *1610*
MSUD express 15(VF)..... *1610*
MSUD Lophlex LQ 20(SB)..... *1610*
MSUD Lophlex(SB) *1610*
MSUD Maxamum(SB) *1610*
MUPIROCIN
.Repatriation Pharmaceutical Benefits Scheme 1662
.RESPIRATORY SYSTEM..... 1517
Mupirocin Nasal (Medsurge)(DZ)..... *1517*
Murelax(RW).....*1483*, *1484*, *1643*
MYCOBACTERIUM BOVIS BCG DANISH STRAIN..... 467
MYCOBACTERIUM BOVIS BCG TICE STRAIN..... 467
MycoCept (RF) *478*, *479*
Myconail(AE) *1659*
MYCOPHENOLATE 478, 479
Mycophenolate APOTEX(GX) *478*, *479*
Mycophenolate GH (GQ) *478*, *479*
Mycophenolate Sandoz(SZ) *478*, *479*
Mycophenolic Acid ARX(XT)..... *478*, *479*
Mycostatin Oral Drops(LN) *1653*
MYCOTEX (CR) *478*, *479*
Myfortic (NV)..... *478*, *479*
Myfortic(NV)..... *478*, *479*
Myleran(AS) *313*
Mysoline(LM).....*1432*
NAFARELIN 260
NALOXONE 28, 1576
Naloxone Hydrochloride (DBL)(PF).....*28*, *1576*
Naloxone Juno (JU).....*28*, *1576*
NALOXONE SXP(XN).....*28*, *1576*
NALTREXONE 1511
Naltrexone GH (GQ).....*1511*
Naprosyn SR1000(IX) *1357*, *1624*
Naprosyn SR750(IX) *1357*, *1358*, *1624*
Naprosyn(IX) *1357*, *1358*, *1624*
NAPROXEN 1357, 1358, 1624
Naramig(AS).....*1427*
NARATRIPTAN 1426, 1427
NARCAN(FF) *28*
Nardil (Canada)(DZ).....*1492*
Nardil(LM).....*1491*
Natrilix SR(SE) *144*
Navelbine(FB) *321*
Nebilet (FK) *153*
NEBIVOLOL 152, 153
Nebivolol Lupin(GQ).....*153*
Nebivolol Sandoz (SZ).....*153*
Neo-B12 (PF) *127*
Neo-B12(PF) *1658*
Neocate Gold(SB) *1588*, *1589*, *1590*
Neocate Junior Vanilla(SB) *1583*, *1584*, *1585*
Neocate Junior(SB) *1598*, *1600*
Neocate LCP(SB).....*1586*, *1587*
Neocate Syneo(SB).....*1600*, *1601*, *1602*
Neo-Mercazole(GH) *269*
Neoral 10(NV) *1230*, *1231*
Neoral 100(NV) *1230*, *1231*
Neoral 25(NV) *1230*, *1231*
Neoral 50(NV) *1230*, *1231*
Neoral(NV) *1230*, *1231*
Neotigason(TB) *221*
Nepiten(AF) *153*
Nesina Met 12.5/1000(TK) *77*, *78*
Nesina Met 12.5/500(TK) *77*, *78*
Nesina Met 12.5/850(TK) *77*, *78*
Nesina(TK) *89*, *90*
NETUPITANT + PALONOSETRON 52
Neulactil(IX).....*1466*
Neupro(UC) *1464*
Neuroccord(CR) *1425*, *1426*
Neurontin (UJ) *1441*, *1673*
Neurontin(UJ)
.Repatriation Pharmaceutical Benefits Scheme.....*1673*
Neurontin(UJ)
.NERVOUS SYSTEM *1441*
Nexavar(BN).....*423*, *424*
Nexazole (RW) *37*, *38*, *39*, *40*
Nexcare Durable Cloth First Aid Tape 799(MM).....*1701*
Nexcare Gentle Paper First Aid Tape 789(MM) *1701*
Nexcare Tegaderm Transparent H1624(MM).....*1685*
Nexcare Tegaderm Transparent H1626(MM).....*1685*
Nexium Hp7(AP) *50*
Nexium(AP) *37*, *38*, *39*, *40*
Nexole(RF) *37*, *38*, *39*, *40*
Nicabate P(GJ).....*1509*
NICORANDIL 134
nicorette 16hr Invisipatch(JT) *1509*
NICOTINE 1509, 1675
Nicotinell Step 1(ON).....*1509*
Nicotinell Step 2(ON).....*1509*
Nicotinell Step 3(ON).....*1509*
Nidem (RW).....*75*, *76*
NIFEDIPINE 156, 157

NILOTINIB 362, 363, 364, 365, 366, 367, 368
Nilstat(AS)
.Repatriation Pharmaceutical Benefits Scheme *1664*
Nilstat(AS)
.ALIMENTARY TRACT AND METABOLISM *61*
NINTEDANIB 417, 419
NIRAPARIB 437, 438, 439, 440, 441, 442, 443
NIRMATRELVIR (&) RITONAVIR 28, 309
NITRAZEPAM
.NERVOUS SYSTEM 1434, 1484
.Palliative Care 1643
NITROFURANTOIN 296
Nitrofurantoin BNM (BZ) *296*
Nitrolingual Pumpspray(SW) *27*, *133*
Nizac(RF) *36*
NIZATIDINE 36
Nolvadex-D(AP) *456*, *457*
Nordip (AF) *155*
Nordip(AF) *155*
NORETHISTERONE
.GENITO URINARY SYSTEM AND SEX HORMONES 241, 248
NORETHISTERONE + ETHINYLESTRADIOL 240
NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL 250
NORFLOXACIN 294
Noriday 28 Day(PF) *241*
Norimin 28 Day(FZ) *240*
Norimin-1 28 Day(FZ) *240*
Normison(AS) *1484*, *1485*, *1643*
Norprolac(FP) *239*
Norspan (MF) *1416*, *1641*
Norspan(MF) *1416*, *1641*
NORTRIPTYLINE 1487
NortriTABS 10 mg(GH) *1488*
NortriTABS 25 mg(GH) *1488*
Norvasc(AS) *155*
Noten (AF) *149*, *150*
NOUMED ALLOPURINOL (VO) *1360*, *1361*
NOUMED AMLODIPINE (VO) *155*
NOUMED AMLODIPINE(VO) *155*
NOUMED AMOXICILLIN (VO) *274*, *275*, *276*
NOUMED ATORVASTATIN (VO) *186*, *187*
NOUMED ATORVASTATIN(VO) *187*
NOUMED AZATHIOPRINE(VO) *1349*
NOUMED BISOPROLOL(VO) *150*, *151*
NOUMED CANDESARTAN/HCT(VO) *174*, *175*
NOUMED CEFALEXIN(VO) *282*, *283*
NOUMED CELECOXIB(VO) *1359*
NOUMED CIPROFLOXACIN (VO) *293*
NOUMED CIPROFLOXACIN(VO) *293*
NOUMED CITALOPRAM (VO) *1488*
NOUMED CITALOPRAM(VO) *1488*
NOUMED CLARITHROMYCIN (VO) *288*
NOUMED DIAZEPAM (VO) *1482*, *1483*, *1643*
NOUMED DONEPEZIL(VO) *1502*, *1503*
NOUMED ESCITALOPRAM (VO) *1489*
NOUMED ESCITALOPRAM(VO) *1488*, *1489*
NOUMED ESOMEPRAZOLE (VO) *37*, *38*, *39*, *40*
NOUMED FLUOXETINE (VO) *1490*
NOUMED FUROSEMIDE(VO) *144*, *145*
Noumed Irbesartan (VO) *171*, *172*
NOUMED LAMOTRIGINE(VO) *1447*, *1448*
NOUMED LANSOPRAZOLE(VO) *41*, *42*, *43*
NOUMED LEVETIRACETAM (VO) *1448*, *1449*
NOUMED LEVETIRACETAM(VO) *1449*, *1450*
NOUMED METOPROLOL(VO) *152*
NOUMED MIRTAZAPINE (VO) *1494*
NOUMED OLANZAPINE (VO) *1468*, *1469*
NOUMED OLANZAPINE(VO) *1469*
NOUMED PANTOPRAZOLE(VO) *46*, *47*, *48*
Noumed Paroxetine(VO) *1491*
NOUMED PREGABALIN (VO) *1425*, *1426*
Noumed Rabeprazole (VO) *48*, *49*, *50*
NOUMED RISPERIDONE (VO) *1476*, *1477*, *1478*, *1479*, *1480*, *1481*, *1482*
NOUMED SERTRALINE(VO) *1491*
NOUMED Sildenafil(VO) *1666*
NOUMED SIMVASTATIN (VO) *190*, *191*
NOUMED TELMISARTAN(VO) *173*
NOUMED TERBINAFINE(VO) *220*
Novasone (AF) *229*, *230*
Novasone(AF) *229*, *230*, *231*
Novatears(AE) *1573*
NovoMix 30 FlexPen(NF) *73*
NovoMix 30 Penfill 3 mL(NO) *72*
NovoRapid FlexPen(NF) *72*
NovoRapid Penfill 3 mL(NO) *71*
NovoRapid(NO) *71*
Noxicid Caps(AL) *37*, *38*, *39*, *40*, *41*
Nubeqa(BN) *460*
Nuelin(IL) *1539*
Nuelin-SR 200(IL) *1539*
Nuelin-SR 250(IL) *1539*
Nuelin-SR 300(IL) *1539*
Nufloxib (AF) *294*
Nu-Gel 2497(KI) *1696*
Nupentin 100 (AF)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Nupentin 100(AF)
.NERVOUS SYSTEM *1441*
Nupentin 300 (AF)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Nupentin 300(AF)
.NERVOUS SYSTEM *1441*
Nupentin 400 (AF)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Nupentin 400(AF)
.NERVOUS SYSTEM *1441*
Nutrini Peptisorb Energy(NU) *1583*
Nutrini Peptisorb(SB) *1596*
Nuvigil(TB) *1496*
NYSTATIN
.ALIMENTARY TRACT AND METABOLISM 61
.Repatriation Pharmaceutical Benefits Scheme 1653, 1664
Nyxoid (UK)(QY) *1576*
Nyxoid(MF) *1576*
O.R.S.(AF) *62*
OBETICHOLIC ACID 57, 58
Ocaliva(EU) *57*, *58*
Ocuflox(VE) *1542*
Odaplix SR (AF) *144*
Odomzo(RA) *435*
OFATUMUMAB 1337
Ofev(BY) *418*, *420*
OFLOXACIN 1542
Olamlo HCT 20/5/12.5 (AL) *184*
Olamlo HCT 40/10/12.5 (AL) *184*, *185*
Olamlo HCT 40/10/25 (AL) *184*, *185*
Olamlo HCT 40/5/12.5 (AL) *184*, *185*
Olamlo HCT 40/5/25 (AL) *184*, *185*
OLANZAPINE 1468, 1469, 1470
Olanzapine APOTEX (GX) *1469*
Olanzapine APOTEX(GX) *1468*, *1469*
Olanzapine ODT generichealth 10 (GQ) *1470*
Olanzapine RBX (RA) *1468*, *1469*
Olanzapine RBX(RA) *1469*
Olanzapine Sandoz (SZ) *1469*
Olanzapine Sandoz ODT 10(SZ) *1470*

Olanzapine Sandoz ODT 15 (SZ) *1470*
Olanzapine Sandoz ODT 20 (SZ) *1470*
Olanzapine Sandoz ODT 5 (SZ) *1469*
Olanzapine Sandoz(SZ) *1468*, *1469*
OLAPARIB 444, 445, 446, 447
Olmekar HCT 20/5/12.5(RF) *184*
Olmekar HCT 40/10/12.5(RF) *184*, *185*
Olmekar HCT 40/10/25(RF) *184*, *185*
Olmekar HCT 40/5/12.5(RF) *184*, *185*
Olmekar HCT 40/5/25(RF) *184*, *185*
OLMEKAR(RW) *181*, *182*
OLMERTAN (RW) *172*, *173*
OLMERTAN COMBI 20/12.5(RW) *176*, *177*
OLMERTAN COMBI 40/12.5(RW) *177*
OLMERTAN COMBI 40/25(RW) *177*
OLMESARTAN 172
Olmesartan - MYL(AF) *172*, *173*
OLMESARTAN + AMLODIPINE 180, 181
OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE 184, 185
OLMESARTAN + HYDROCHLOROTHIAZIDE 176, 177
Olmesartan HCT - MYL 20/12.5 (AF) *176*, *177*
Olmesartan HCT - MYL 40/12.5 (AF) *177*
Olmesartan HCT - MYL 40/25 (AF) *177*
Olmesartan Sandoz (SZ) *172*, *173*
Olmesartan/Amlodipine - MYL 20/5(AF) *181*
Olmesartan/Amlodipine - MYL 40/10(AF) *181*
Olmesartan/Amlodipine - MYL 40/5(AF) *181*, *182*
Olmesartan/Amlodipine 20/5 APOTEX (TX) *181*
Olmesartan/Amlodipine 40/10 APOTEX (TX) *181*
Olmesartan/Amlodipine 40/5 APOTEX (TX) *181*, *182*
Olmesartan/Amlodipine Sandoz (SZ) *181*, *182*
Olmesartan/HCT Sandoz(SZ) *176*, *177*
Olmetec Plus(AL) *176*, *177*
Olmetec(AL) *172*, *173*
OLSALAZINE 70
Olsetan(MQ) *172*, *173*
Olumiant(LY) *1241*, *1244*, *1248*
Omepral (FQ) *43*, *44*, *45*
OMEPRAZOLE 43, 44, 45
Omeprazole Sandoz(HX) *43*, *44*, *45*
Omeprazole Sandoz(SZ) *43*, *44*, *45*
Onbrez(NV) *1518*
OncoTICE(MK) *467*
ONDANSETRON 52, 53, 54
Ondansetron Mylan ODT (AF) *53*, *54*
Ondansetron Mylan Tablets (AF) *52*, *53*
Ondansetron ODT Lupin (HQ) *54*
Ondansetron ODT Viatris (AL) *53*
Ondansetron ODT Viatris(AL) *54*
Ondansetron ODT-DRLA(RZ) *53*, *54*
Ondansetron SZ ODT (HX) *53*, *54*
Ondansetron SZ ODT(HX) *53*, *54*
Ondansetron SZ(HX) *53*
Ondansetron Tablets Viatris (AL) *53*
Ondansetron-DRLA(RZ) *52*, *53*
Ongentys(XY) *1465*
Onglyza(AP) *92*
Onureg(CJ) *316*, *317*
OPICAPONE 1465
Op-Site Flexigrid 4629(SN) *1685*
Optifresh eye gel(PP) *1566*, *1567*
Optisulin SoloStar(WA) *74*
Optisulin(GZ) *73*
Optive(VE) *1568*
Optix(PP) *1573*, *1574*
Orabase(AS) *1660*
Oratane (RF) *232*
Oratane(OU) *232*
Oratane(RF) *232*
Ordine 10(XT) *1383*, *1396*, *1628*
Ordine 2(XT) *1383*, *1395*
Ordine 5(XT) *1382*, *1391*, *1629*
Orencia ClickJect(BQ) *469*, *472*, *477*
Orencia(BQ) *469*, *472*, *477*
Oripro(ON) *248*
ORLISTAT 1655
Oroxine(AS) *267*, *268*
ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL 1677
Orudis SR 200(SW) *1357*
Oruvail SR(AV) *1357*
OSIMERTINIB 378, 379, 380
OsmoLax(KY) *60*, *1623*
Ospolot(FF) *1453*, *1454*
Osteomol 665 Paracetamol (CR) *1425*, *1641*
Osteomol 665 Paracetamol(CR) *1425*, *1641*, *1673*
Osteovan (SZ) *1366*
Otezla(AN) *477*
Otocomb Otic(LN) *1575*
Otodex(AV) *1575*
Ovaleap(TT) *251*
Ovestin Ovula(AS) *247*
Ovestin(AS) *247*
Ovidrel(SG) *250*
OXAZEPAM 1483, 1643
OXCARBAZEPINE 1435, 1436
Oxis Turbuhaler(AP) *1517*
OXPRENOLOL 149
OXYBUTYNIN 254
OXYCODONE 1396, 1397, 1398, 1399, 1401, 1630
OXYCODONE + NALOXONE 1402, 1631
Oxycodone Sandoz(SZ) *1402*, *1631*
Oxycodone Viatris (MQ) *1397*, *1401*
Oxycodone Viatris(MQ) *1397*, *1398*
OxyContin (MF) *1402*, *1631*
OxyContin(MF) *1402*, *1631*
OXYMETAZOLINE 1675
Oxyndone(TX) *1397*, *1401*
OxyNorm Liquid 1mg/mL(MF) *1397*, *1400*
OxyNorm(MF) *1397*, *1398*, *1400*
Oxytrol(TT) *254*, *255*
OZANIMOD 1233, 1234, 1236
Ozempic(NO) *96*
Ozidal(RA) *1476*, *1477*, *1478*, *1479*, *1480*, *1481*, *1482*
Ozin 10 (ZS) *1469*
Ozin 2.5 (ZS) *1468*
Ozin 5(ZS) *1469*
Ozin 7.5 (ZS) *1469*
Ozmep(RW) *43*, *44*, *45*
Ozole(RA) *297*
Ozpan (RA) *46*, *47*, *48*
Ozurdex(VE) *1542*, *1543*, *1545*
PAA (UL) *1566*, *1567*
Pacrolim(AF) *1231*, *1232*
PAD WOUND DEBRIDEMENT 1700
Paediatric Seravit(SB) *1619*
PALBOCICLIB 391
Palexia SR(CS) *1420*
PALIPERIDONE 1474, 1475, 1476
PALONOSETRON 54
Palonosetron Dr.Reddy's (RZ) *54*
PALONOSETRON Medsurge(DZ) *54*
PAMIDRONATE DISODIUM 1363
Pamisol(PF) *1364*
Panadeine Forte(SW) *1416*, *1417*, *1418*
Panadol(GJ) *1641*
Panafcort(AS) *265*
Panafcortelone(AS) *264*

Panamax 240 Elixir(SW) *1424*, *1672*
Panamax Co. 40(SW) *1672*
Panamax(SW) *1424*, *1425*, *1673*
PANCREATIC EXTRACT 71
PANTHENOL 1664
Panthron(ZS) *46*, *47*, *48*
PANTOPRAZOLE 45, 46, 47
Pantoprazole APOTEX (TY) *46*, *47*, *48*
Pantoprazole generichealth(HQ) *46*, *47*, *48*
Pantoprazole Sandoz (SZ) *46*, *47*, *48*
PAPER WASP VENOM 1575
PARACETAMOL 1424, 1425, 1641, 1672, 1673
Paracetamol (Sandoz) (SZ) *1424*, *1425*, *1673*
PARACETAMOL + CODEINE 1416, 1417, 1672
Paracetamol Sandoz Pharma(QS) *1424*, *1425*, *1673*
Paracetamol/Codeine GH 500/30 (GQ) *1416*, *1417*, *1418*
PARAFFIN 1572, 1573
Paralgin (OW) *1424*, *1425*, *1673*
Parapane OSTEO (AF) *1425*, *1641*, *1673*
Parapane OSTEO(AF) *1425*, *1641*
Parapane(AF) *1424*, *1425*, *1673*
Parbezol (RW) *48*
Parbezol(RW) *48*, *49*, *50*
Pariet(JC) *48*, *49*, *50*
Parlodel(SZ)
.GENITO URINARY SYSTEM AND SEX HORMONES *237*, *238*
.NERVOUS SYSTEM *1461*, *1462*
Parnate(GH) *1492*
PAROXETINE 1490
Paroxetine GH (GQ) *1491*
Paroxetine Sandoz(SZ) *1491*
PATIROMER 1577, 1578
PAVTIDE ACCUHALER 100/50(TX) *1527*
PAVTIDE ACCUHALER 250/50 (TX) *1527*
PAVTIDE ACCUHALER 500/50 (TX) *1528*
PAVTIDE MDI 50/25(TX) *1527*
Pavtide(TX) *1527*, *1528*
Paxam 0.5(AF) *1434*, *1642*
Paxam 2(AF) *1434*, *1642*
Paxlovid(PF) *28*, *311*
Paxtine (AF) *1491*
PAZOPANIB 420, 421, 422
Peg 7420(MM) *1679*
Peg 7422(MM) *1679*
Peg 7423(MM) *1679*
Peg 7425(MM) *1679*
Pegasys(XO) *466*
PEGINTERFERON ALFA-2A 466
PEGINTERFERON BETA-1A 466
Pemzo (RW) *43*, *44*, *45*
PENICILLAMINE 1359
Pentasa(FP) *66*, *67*, *68*, *69*
Penthrox(DV) *27*
Peptamen Junior(NT) *1596*
PERAMPANEL 1450, 1451, 1452
PERFLUOROHEXYLOCTANE 1573
PERHEXILINE 134
PERICIAZINE 1466
Perindo (AF) *160*, *161*
Perindo Combi 4/1.25(AF) *166*
PERINDOPRIL 159, 160, 161
PERINDOPRIL + AMLODIPINE 167, 168
PERINDOPRIL + INDAPAMIDE 165, 166
Perindopril Arginine Sandoz(SZ) *159*, *160*, *161*
PERISYL COMBI 4/1.25 (AL) *166*
PERISYL(AL) *160*, *161*
PERMETHRIN 1517
Petrus Bisacodyl Suppositories(PP) *60*, *1653*, *1654*
Petrus Pharmaceuticals Pty Ltd(PP) *1654*
Pexsig(AS) *134*
Pfizer Australia Pty Ltd(PF)
.Prescriber Bag *28*
Pfizer Australia Pty Ltd(PF)
.ANTIINFECTIVES FOR SYSTEMIC USE *290*
Pfizer Australia Pty Ltd(PF)
.ANTIINFECTIVES FOR SYSTEMIC USE *291*
Pharmacor Amlodipine (CR) *155*
Pharmacor Amlodipine(CR) *155*
Pharmacor Atorvastatin (CR) *187*
Pharmacor Atorvastatin(CR) *186*, *187*
Pharmacor Cefuroxime(CR) *285*
Pharmacor Cinacalcet (CR) *271*
Pharmacor Cinacalcet(CR) *271*
Pharmacor Cyproterone 100(CR)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *459*
.GENITO URINARY SYSTEM AND SEX HORMONES *253*
Pharmacor Cyproterone 50(CR)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *459*
.GENITO URINARY SYSTEM AND SEX HORMONES *253*, *254*
PHARMACOR DABIGATRAN (CR) *115*
PHARMACOR DABIGATRAN(CR) *115*, *116*
Pharmacor Dimethyl Fumarate (CR) *1349*, *1350*
Pharmacor Ezetimibe 10(CR) *201*, *202*
Pharmacor Ezetimibe Rosuvastatin Composite Pack (CR) *208*, *210*
Pharmacor Ezetimibe Simvastatin 10/10(CR) *216*, *217*
Pharmacor Ezetimibe Simvastatin 10/20(CR) *216*, *217*
Pharmacor Ezetimibe Simvastatin 10/40(CR) *215*, *218*
Pharmacor Ezetimibe Simvastatin 10/80(CR) *215*, *217*
Pharmacor Finasteride 5 (CR) *1669*
Pharmacor Fingolimod (CR) *1233*
Pharmacor Gabapentin 600 (CR)
.NERVOUS SYSTEM *1441*
Pharmacor Gabapentin 600(CR)
.Repatriation Pharmaceutical Benefits Scheme *1673*
Pharmacor Gabapentin 800 (CR)
.NERVOUS SYSTEM *1441*
Pharmacor Gabapentin 800(CR)
.Repatriation Pharmaceutical Benefits Scheme *1674*
Pharmacor Gliclazide MR (CR) *75*
Pharmacor Gliclazide MR(CR) *75*, *76*
Pharmacor Isotretinoin (CR) *232*
Pharmacor Letrozole 2.5(CR) *463*, *464*
Pharmacor Lurasidone(CR) *1467*
Pharmacor Meloxicam 15(CR) *1355*
Pharmacor Meloxicam 7.5(CR) *1355*
Pharmacor Metformin XR (CR) *74*, *75*
Pharmacor Metformin XR(CR) *74*, *75*
Pharmacor Mycophenolate (CR) *478*
Pharmacor Mycophenolate 250 (CR) *479*
Pharmacor Mycophenolate 500 (CR) *478*, *479*
Pharmacor Olmesartan 20 (CR) *172*
Pharmacor Olmesartan 40 (CR) *172*, *173*
Pharmacor Olmesartan Amlodipine 20/5(CR) *181*
Pharmacor Olmesartan Amlodipine 40/10(CR) *181*, *182*
Pharmacor Olmesartan Amlodipine 40/5(CR) *181*, *182*
Pharmacor Olmesartan HCTZ 20/12.5 (CR) *176*, *177*
Pharmacor Olmesartan HCTZ 40/12.5 (CR) *177*
Pharmacor Olmesartan HCTZ 40/25 (CR) *177*
Pharmacor Omeprazole 20(CR) *43*, *44*, *45*
Pharmacor Posaconazole(CR) *299*
Pharmacor Quetiapine 100 (CR) *1471*
Pharmacor Quetiapine 200 (CR) *1471*
Pharmacor Quetiapine 25 (CR) *1472*
Pharmacor Quetiapine 300 (CR) *1472*

Pharmacor Rasagiline (CR) *1464*
Pharmacor Riluzole (CR) *1512*
Pharmacor Rosuvastatin 10(CR) *189*
Pharmacor Rosuvastatin 20(CR) *189*, *190*
Pharmacor Rosuvastatin 40(CR) *189*, *190*
Pharmacor Rosuvastatin 5 (CR) *189*, *190*
Pharmacor Sumatriptan 50(CR) *1428*
Pharmacor Tacrolimus 0.5 (CR) *1231*, *1232*
Pharmacor Tacrolimus 1 (CR) *1231*, *1232*
Pharmacor Tacrolimus 5(CR) *1231*, *1232*
Pharmacor Telmisartan 40 (CR) *173*
Pharmacor Telmisartan 80 (CR) *173*
Pharmacor Teriflunomide (CR) *1349*
PHARMACOR VARENICLINE (CR) *1510*, *1511*
Pharmacor Zopiclone (CR) *1675*
Pharmacy Action Anti-Fungal Cream(GQ) *1659*
Pharmacy Action Anti-Fungal Nail Treatment (GQ) *1659*
Pharmacy Action Cetrelief(GQ) *1676*
Pharmacy Action Colox-Senna(HQ) *1654*
Pharmacy Action Cystitis Relief(GQ) *1667*
Pharmacy Action Diarrhoea Relief (GQ) *1655*
Pharmacy Action FemCream (GQ) *1665*
Pharmacy Action FemCream 3 Day Cream(GQ) *1664*
Pharmacy Action Fexorelief 120(GQ) *1676*
Pharmacy Action Hydrocortisone Cream 1%(GQ) *1662*
Pharmacy Action Laxative with Senna (GQ) *1654*
Pharmacy Action Lorastyne(GQ) *1676*
Pharmacy Action Low Dose Aspirin (GQ) *1658*
Pharmacy Action Nasal Decongestant(GQ) *1676*
Pharmacy Action Nystatin Oral Drops(GQ) *1653*
Pharmacy Action OSTEO Relief 665(HQ) *1673*
Pharmacy Action Paracetamol Osteo 665 (GQ) *1673*
Pharmacy Action Pharmisil (GQ) *1660*
Pharmacy Action Sinus & Nasal Decongestant Relief(GQ) *1676*
Pharmacy Action Worm Treatment(GQ) *1675*
Pharmacy Care Magnesium (SI) *1657*
PHARMACY CARE PARACETAMOL (SI) *1424*, *1425*, *1673*
Phebra Naproxen Suspension(FF) *1357*, *1624*
Pheburane(OH) *109*
PHENELZINE 1491
Phenobarb(RW) *1432*
PHENOBARBITAL 1431
Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd)(AS) *1432*
PHENOXYBENZAMINE
.CARDIOVASCULAR SYSTEM 149
.GENITO URINARY SYSTEM AND SEX HORMONES 255
PHENOXYMETHYLPENICILLIN 277, 278
Phenoxymethylpenicillin-AFT(AE) *277*
Phenylalanine 50(VF) *1617*
PHENYLALANINE WITH CARBOHYDRATE 1617
PHENYTOIN 1432
Phlexy-10(SB) *1612*
Phlexy-Vits(SB) *1619*
PHOSPHATE PHEBRA(FG) *1580*, *1581*
PHOSPHORUS 1580
Physeptone(AS) *1413*, *1414*, *1640*
Physiotens (GO) *142*
PHYTOMENADIONE 29
Piax (AF) *112*, *1658*
Piax Plus Aspirin(AF) *112*, *113*
PILOCARPINE 1547
PIMECROLIMUS 235
Pinetarsol(EO) *1661*
PIOGLITAZONE 88, 89
Pirfenidet(AF) *1352*, *1353*
PIRFENIDONE 1352
Pirfenidone Ameda (XT) *1352*, *1353*
Pirfenidone Dr.Reddy's(RZ) *1352*, *1353*
Pirfenidone Sandoz (SZ) *1352*, *1353*
PIROXICAM 1355
PIZOTIFEN 1431
PKU Air 20(VF) *1608*
PKU Anamix First Spoon(SB) *1611*
PKU Anamix infant(SB) *1611*
PKU Anamix Junior LQ(SB) *1608*
PKU Anamix Junior(SB) *1609*
PKU Build 10(QH) *1614*
PKU Build 20(QH) *1614*
PKU Cooler 10(VF) *1608*
PKU Cooler 15(VF) *1608*
PKU Cooler 20(VF) *1608*
PKU Easy Microtabs(OH) *1603*
PKU Easy Shake & Go(OH) *1603*
PKU Easy Tablet(OH) *1602*
PKU Easy(OH) *1617*
PKU Explore 10(VF) *1611*
PKU Explore 5(VF) *1611*
PKU express 15(VF) *1609*
PKU express 20(VF) *1609*
PKU Glytactin RTD 15 Lite(QH) *1614*
PKU Glytactin RTD 15(QH) *1614*
PKU GMPro LQ(SB) *1615*
PKU Go(OH) *1603*
PKU Lophlex LQ 10(SB) *1608*
PKU Lophlex LQ 20(SB) *1608*
PKU Lophlex Sensation 20(SB) *1609*
PKU Lophlex(SB) *1609*
PKU Restore(QH) *1614*
PKU Sphere Liquid(VF) *1615*
PKU Sphere15(VF) *1615*
PKU Sphere20(VF) *1615*
PKU squeezie(VF) *1608*
PKU Start(VF) *1611*
Placil (AF) *1487*
Plaqacide(OB) *1653*
Plaquenil (SW) *1359*
Plavicor 75(CR) *112*, *1658*
Plegridy(BD) *466*, *467*
Plendil ER(GX) *155*, *156*
Plidogrel (RF) *1658*
Plidogrel(RF) *112*
pms-HYDROmorphone(DZ) *1377*, *1379*, *1625*
pms-SALBUTAMOL(DZ) *29*, *1518*
Poly Visc(IQ) *1572*, *1573*
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL 1573, 1574
POLYLACTIC ACID 1581
Poly-Tears(IQ) *1570*
PONATINIB 370, 371, 372
Ponstan(PF) *1358*
POSACONAZOLE 299
Posaconazole ARX (XT) *299*
POSACONAZOLE DR.REDDY'S(RZ) *299*
Posaconazole Juno (JU) *299*
Posaconazole Sandoz(SZ) *299*
POTASSIUM CHLORIDE 104
POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE 105
POVIDONE-IODINE
.Repatriation Pharmaceutical Benefits Scheme 1662, 1700
Pradaxa (BY) *115*, *116*
Pradaxa(BY) *115*, *116*
Praluent(SW) *193*, *195*
Pramin(AF) *51*, *1622*
PRAMIPEXOLE 1462, 1463
Pravachol(RW) *188*

PRAVASTATIN 188
Pravastatin Sandoz (SZ) *188*
Pravastatin Sandoz(SZ) *188*
PRAZIQUANTEL 1515
PRAZOSIN 142, 143
Prebalin(RF) *1426*
PredMix(LN) *264*, *265*
Prednefrin Forte(VE) *1546*
PREDNISOLONE 264
PREDNISOLONE ACETATE + PHENYLEPHRINE 1546
PREDNISOLONE SODIUM PHOSPHATE
.ALIMENTARY TRACT AND METABOLISM 65
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS 264
PREDNISONE 265
Predsol(AS) *65*
Predsolone(LN) *264*
Predsone(LN) *265*
PREGABALIN 1425
Pregabalin Lupin(HQ) *1426*
Pregabalin Sandoz (SZ) *1426*
PREGABALIN-DRLA (RZ) *1426*
Prenoxad(FF) *1576*
Presolol 100(AF) *154*, *155*
PREXUM 10 (RX) *160*, *161*
PREXUM 2.5 (RX) *159*, *161*
PREXUM 5 (RX) *160*
Prexum Combi 5/1.25(RX) *166*
PREXUM Combi LD 2.5/0.625(RX) *165*
Prilace (RF) *162*, *163*
Prilace(RF) *162*, *163*
PRIMIDONE 1432
Primolut N(BN) *248*, *249*
Pristiq(PF) *1492*, *1493*
Pritor/Amlodipine(FI) *182*
Pro-Banthine(RW) *255*
PROBENECID 1362
Probitor (SZ) *43*, *44*, *45*
ProCalm (RW) *56*, *57*
PROCHLORPERAZINE 28, 56, 57
Prochlorperazine GH(GQ) *56*, *57*
Pro-Cid(FF) *1362*
Prodeine Forte(AV) *1416*, *1417*, *1418*
Profore 66050016(SN) *1679*
Profore Lite 66050415(SN) *1679*
PROGESTERONE 248
Progout 100(AF) *1360*, *1361*
Progout 300(AF) *1361*
Prograf (LL) *1231*, *1232*
Prograf(LL) *1231*, *1232*
Progynova(BN) *245*, *246*
Proladone(FF) *1397*, *1399*
Prolia(AN) *1371*
PROMETHAZINE
.ALIMENTARY TRACT AND METABOLISM 57
.Prescriber Bag 29
.RESPIRATORY SYSTEM 1540
Prontosan Wound Irrigation Solution(BR) *1682*
PROPANTHELINE 255
PROPRANOLOL 149
PROPYLTHIOURACIL 269
Proscar(OQ) *1669*
Protaphane (NO) *72*
Protaphane InnoLet(NI) *72*
Protaphane Penfill 3 mL (NO) *72*
PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID 1617
PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC 1677
PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS 1582
PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A 1617
PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES 1593, 1594
Provera(PF)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *451*, *452*
.GENITO URINARY SYSTEM AND SEX HORMONES *247*, *248*
Proxen SR 1000(IY) *1357*, *1624*
Proxen SR 750(IY) *1357*, *1358*, *1624*
Prozac 20(LY) *1490*
ProZero(VF) *1618*
PRYZEX (RW) *1469*
PRYZEX ODT (RW) *1470*
PRYZEX ODT(RW) *1469*, *1470*
PRYZEX(RW) *1469*
PSEUDOEPHEDRINE 1676
PSYLLIUM HUSK POWDER 1654
PTU(FF) *269*
Pulmicort Respules(AP) *1534*
Pulmicort Turbuhaler(AP) *1533*, *1534*
Puregon 300 IU/0.36 mL(OQ) *252*
Puregon 600 IU/0.72 mL(OQ) *252*
Puregon 900 IU/1.08 mL(OQ) *252*
Purinethol(AS) *315*
Putter Pro 2 931685(HR) *1678*
Pyralin EN(FZ) *70*
PYRANTEL 1516
PYRIDOSTIGMINE 1508
Qinlock(ZB) *423*
Qtern 5/10(AP) *83*, *84*
Questran Lite(GO) *192*
Quetia 100(RW) *1471*
Quetia 200(RW) *1471*
Quetia 25(RW) *1472*
Quetia 300(RW) *1472*
Quetia XR (OW) *1471*, *1472*
Quetia XR(OW) *1472*
QUETIAPINE 1471, 1472
Quetiapine APOTEX (GX) *1471*, *1472*
Quetiapine RBX(RA) *1471*, *1472*
Quetiapine Sandoz Pharma (HX) *1471*, *1472*
Quetiapine Sandoz XR (SZ) *1472*
Quetiapine Sandoz XR(SZ) *1471*, *1472*
QUETIAPINE-AS XR (RW) *1471*, *1472*
Quilonum SR(AS) *1493*
QUINAGOLIDE 239
QUINAPRIL 161
QUINAPRIL + HYDROCHLOROTHIAZIDE 166
Quinate(RW) *1514*
QUININE 1514
QuitX(AF) *1675*
QV Bath Oil(EO) *1661*
QV Gentle Wash(EO) *1663*
QV Skin Lotion(EO) *1660*
Qvar 100 Autohaler(IL) *1533*
Qvar 100(IL) *1533*
Qvar 50 Autohaler(IL) *1533*
Qvar 50(IL) *1533*
RABEPRAZOLE 48, 49
Rabeprazole Mylan (AF) *48*, *49*, *50*
Rabeprazole Sandoz(SZ) *48*, *49*, *50*
Rabeprazole SUN (RN) *48*, *49*, *50*
Ralovera(FZ) *247*, *248*

RALOVISTA (RF) *1372*
RALOXIFENE 1371, 1372
Raloxifene GH(GQ) *1372*
RAMIPRIL 161, 162, 163
RAMIPRIL + FELODIPINE 168
Ramipril Sandoz (SZ) *162*, *163*
Ramipril Sandoz(SZ) *162*, *163*
Ramipril Viatris (AL) *162*, *163*
Ramipril Viatris(AL) *162*, *163*
Ramipril Winthrop (WA) *162*, *163*
Ramipril Winthrop(WA) *162*, *163*
RA-Morph (NZ)(WZ) ...*1382*, *1383*, *1391*, *1396*, *1628*, *1629*
RANIBIZUMAB .1560, 1561, 1562, 1563, 1564, 1565, 1566
RANITIDINE 37
Rapamune(PF) *1346*
RASAGILINE 1464
Rasagiline Lupin(HQ) *1464*
Rasagiline Sandoz (SZ) *1464*
Rasagiline-Teva(EV) *1464*
RBX Topiramate(RA) *1454*, *1455*, *1456*
RCF(AB) *1618*
Reagila(CS) *1474*
Reandron 1000(AS) *245*
Reaptan 10/10(RX) *167*, *168*
Reaptan 10/5(RX) *167*, *168*
Reaptan 5/10(RX) *167*, *168*
Reaptan 5/5(RX) *167*, *168*
REBOXETINE 1494
Recagon (OV) *252*
Redipred(AS) *264*, *265*
Reedos 100 (ZS) *1447*, *1448*
Reedos 200 (ZS) *1447*, *1448*
Reedos 25 (ZS) *1447*, *1448*
Reedos 50 (ZS) *1447*, *1448*
Refresh Liquigel(VE) *1567*, *1568*
Refresh Night Time(VE) *1572*, *1573*
Refresh Tears Plus(VE) *1567*, *1568*
Relistor(LM) *1623*
Relpax(UJ) *1426*
Remicade(JC) *1671*
Reminyl (JC) *1504*, *1505*
Remsima SC(EW) *1011*, *1012*, *1013*, *1014*, *1015*, *1016*, *1017*, *1019*, *1020*, *1021*, *1023*, *1024*, *1026*, *1028*, *1030*, *1032*, *1034*, *1036*, *1038*, *1040*, *1042*
Renagel(GZ) *1578*, *1579*
Renastart(VF) *1619*
Renastep(VF) *1617*
Renitec 20(AF) *158*
Renitec Plus 20/6 (AF) *164*, *165*
Renitec(AF) *158*
Repatha(AN) *196*, *199*
Replicare Ultra 66000434(SN) *1693*
Resonium-A(SW) *1677*
Resprim Forte (AF) *287*, *288*
Revive Tears (PP) *1571*, *1572*
Rexulti(LU) *1474*
Riamet 20mg/120mg Dispersible(NV) *1514*
Riamet(NV) *1515*
RIBAVIRIN 312
RIBOCICLIB 392, 393, 394
Ridaura(BZ) *1359*
Ridaura(GH) *1359*
Rifadin(SW) *302*
RIFAMPICIN
.ANTIINFECTIVES FOR SYSTEMIC USE 301, 302
RIFAXIMIN 61
Rilast RAPIHALER 100/3(XT) *1520*, *1522*, *1523*
Rilast RAPIHALER 200/6(XT) *1522*, *1524*
Rilast TURBUHALER 200/6(XT) *1521*, *1523*, *1524*
Rilast TURBUHALER 400/12(XT) *1525*
Rilutek(SW) *1512*
RILUZOLE 1511
Riluzole Sandoz (SZ) *1512*
Rimycin 150(AF)
.ANTIINFECTIVES FOR SYSTEMIC USE *301*, *302*
Rimycin 300(AF)
.ANTIINFECTIVES FOR SYSTEMIC USE *301*, *302*
Rinvoq(VE) *1291*, *1293*, *1296*, *1297*, *1300*, *1301*, *1304*, *1305*, *1306*, *1307*, *1310*, *1315*, *1319*, *1322*, *1326*, *1329*, *1332*, *1336*
RIPRETINIB 423
RISANKIZUMAB 1089, 1092
RISEDRONATE 1364, 1365, 1671
Risedronate Sandoz (SZ) *1365*
Risedronate Sandoz(SZ) *1671*
Risedronate-GA (GN) *1671*
Rispa (RW) *1476*, *1477*, *1478*, *1479*, *1480*, *1481*, *1482*
Rispa(RW) *1477*
Risperdal (JC) *1477*
Risperdal Consta(JC) *1478*
Risperdal(JC) ... *1476*, *1477*, *1478*, *1479*, *1480*, *1481*, *1482*
RISPERIDONE 1476, 1477, 1478, 1479, 1480, 1481
Risperidone Sandoz (SZ) *1476*, *1477*, *1478*, *1480*, *1481*
Risperidone Sandoz(SZ) *1477*, *1479*, *1481*, *1482*
Rispernia (ZS) *1477*, *1479*, *1481*, *1482*
Rispernia(ZS) *1476*, *1477*, *1478*, *1480*, *1481*
Ritalin 10(NV) *1498*
Ritalin LA(NV) *1500*
RIVAROXABAN 120, 121, 122, 123, 124
RIVASTIGMINE 1505
Rivotril(PB) *26*, *1433*, *1434*, *1642*
Rixadone (AF) *1476*, *1477*, *1478*, *1480*, *1481*
Rixadone(AF) *1477*, *1479*, *1481*, *1482*
RIXALT (RF) *1428*
RIZATRIPTAN 1427
Rizatriptan ODT APOTEX(GX) *1428*
Rizatriptan ODT GH (GQ) *1428*
Rizatriptan Wafers-10mg(AF) *1427*
Roaccutane(RO) *232*
Rocaltrol(IX)
.ALIMENTARY TRACT AND METABOLISM *103*
.MUSCULO-SKELETAL SYSTEM *1370*
ROMOSOZUMAB 1372
Rosidal TCS 26484(LC) *1678*
ROSUVASTATIN 189
Rosuvastatin APOTEX (GX) *189*, *190*
Rosuvastatin APOTEX(GX) *189*, *190*
Rosuvastatin Lupin (GQ) *189*, *190*
Rosuvastatin Lupin(GQ) *189*, *190*
Rosuvastatin RBX (RA) *189*, *190*
Rosuvastatin RBX(RA) *189*, *190*
Rosuvastatin Sandoz (SZ) *189*, *190*
Rosuvastatin Sandoz(SZ) *189*, *190*
Rosuzet Composite Pack(AL) *208*, *209*, *210*, *211*
ROTIGOTINE 1464
Roxar 150(RW) *289*, *290*
Roxar 300(RW) *289*, *290*
Roxin(RW) *294*
ROXITHROMYCIN 289
Roxithromycin Sandoz (SZ) *289*, *290*
Rozlytrek(RO) *411*
Rubifen LA (AE) *1500*
RUXOLITINIB 399, 400, 401
Ruzurgi(OJ) *1511*
Rynacrom(SW) *1676*
Rythmodan (Canada)(OJ) *130*
Rythmodan(PB) *130*
Ryzodeg Flextouch(NO) *73*
Ryzodeg Penfill(NO) *73*
Sabril(SW) *1438*, *1439*

SACUBITRIL + VALSARTAN 185, 186
SAFINAMIDE 1464
Saflutan(MF) *1551*
Salazopyrin(PF) *70*
Salazopyrin-EN(PF) *70*
SALBUTAMOL
.Prescriber Bag 29
.RESPIRATORY SYSTEM 1518, 1538
Salbutamol Cipla(LR) *29*, *1518*
Salflumix Easyhaler 250/50(OX) *1527*
Salflumix Easyhaler 500/50(OX) *1528*
SALICYLIC ACID + LACTIC ACID 1663
SALMETEROL 1518
Salofalk(FD) *66*, *67*, *68*, *69*, *70*
SalplusF DPI 250/50 (SZ) *1527*
SalplusF DPI 500/50 (SZ) *1528*
SalplusF Inhaler 125/25 (SZ) *1527*
SalplusF Inhaler 250/25 (SZ) *1528*
Salpraz(AF) *46*, *47*, *48*
Sandomigran 0.5(AE) *1431*
Sandoz Lamotrigine(HX) *1447*, *1448*
Sandoz Venlafaxine XR(HX) *1494*, *1495*
Sandrena(OX) *245*, *246*
Saphris(OQ) *1468*
SAPROPTERIN 105, 106, 107, 108
Savacol Mouth and Throat Rinse(OM) *1653*
SAXAGLIPTIN 91, 92
SAXAGLIPTIN + DAPAGLIFLOZIN 83
SAXAGLIPTIN + METFORMIN 84
Scemblix(NV) *321*, *322*, *324*
Sculptra(GA) *1581*
SebiRinse(EO) *1664*
Sebitar(EO) *1663*
SECUKINUMAB 1099, 1100, 1101, 1103, 1104, 1106, 1108, 1109, 1111, 1114, 1117, 1120, 1123, 1127, 1130, 1134
seebri breezhaler(NV) *1535*
SELEGILINE 1465
SELENIUM SULFIDE 1663
Selsun(DQ) *1663*
SEMAGLUTIDE 96
Senna-Gen(PP) *1654*
SENNOSIDE B 1654
Senokot(RC) *1654*
Septrin Forte(RW) *287*, *288*
Septrin(RW) *287*
Serenace(AS) *26*, *1466*, *1642*
Serepax (AS) *1483*, *1484*, *1643*
Serepax(AS) *1483*, *1484*, *1643*
Seretide Accuhaler 100/50(GK) *1527*
Seretide Accuhaler 250/50(GK) *1527*
Seretide Accuhaler 500/50(GK) *1528*
Seretide MDI 125/25(GK) *1527*
Seretide MDI 250/25(GK) *1528*
Seretide MDI 50/25(GK) *1527*
Serevent Accuhaler(GK) *1519*
Seroquel XR(AL) *1471*, *1472*
Seroquel(AL) *1471*, *1472*, *1473*
Sertra 100 (RW) *1491*
Sertra 50 (RW) *1491*
SERTRALINE 1491
Sertraline generichealth(GQ) *1491*
Sertraline Sandoz (SZ) *1491*
Setopress 3505(MH) *1679*
Setrona(RA) *1491*
SEVELAMER 1578, 1579
Sevelamer Apotex (TX) *1578*, *1579*
Sevelamer Lupin(GQ) *1578*, *1579*
Sevikar 20/5(AL) *181*
Sevikar 40/10(AL) *181*, *182*
Sevikar 40/5(AL) *181*, *182*
Sevikar HCT 20/5/12.5 (AF) *184*
Sevikar HCT 40/10/12.5(AF) *184*, *185*
Sevikar HCT 40/10/25(AF) *184*, *185*
Sevikar HCT 40/5/12.5(AF) *184*, *185*
Sevikar HCT 40/5/25(AF) *184*, *185*
Sevredol(MF) *1386*, *1626*
Shilova 500 (ZS) *308*
Sical(AF)
.ALIMENTARY TRACT AND METABOLISM *102*, *103*
.MUSCULO-SKELETAL SYSTEM *1370*
Sifrol (BY) *1462*, *1463*, *1464*
Sifrol ER (BY) *1463*
Sigmacort(AS) *222*
Sigmaxin(LN) *130*
Sigmaxin-PG(LN) *130*
SILDENAFIL
.Repatriation Pharmaceutical Benefits Scheme 1666
Sildenafil APOTEX (GX) *1666*
Sildenafil APOTEX(GX) *1666*
Sildenafil generichealth(GQ) *1666*
Sildenafil Lupin (HQ) *1666*
Sildenafil Lupin(HQ) *1666*
Sildenafil Sandoz (SZ) *1666*
Sildenafil Sandoz(SZ) *1666*
SILODOSIN 1667, 1668
SILVER SULFADIAZINE 221
Simbrinza 1%/0.2%(NV) *1548*
Simipex 0.125(RW) *1463*, *1464*
Simipex 0.25(RW) *1463*, *1464*
Simipex 1(RW) *1463*
SIMIPEX XR(RW) *1463*
Simponi(JC) ... *978*, *980*, *982*, *985*, *987*, *989*, *990*, *993*, *997*, *1001*, *1006*, *1010*
Simpral (AF) *1463*, *1464*
Simvar 10(RW) *190*
Simvar 20(RW) *190*, *191*
Simvar 40(RW) *190*, *191*
Simvar 80 (RW) *190*, *191*
SIMVASTATIN 190
Simvastatin Sandoz (SZ) *190*, *191*
Simvastatin Sandoz(SZ) *190*, *191*
SINADOPA 100/25(RW) *1458*
SINADOPA 250/25 (RW) *1458*
Sinemet 100/25 (AL) *1458*
Sinemet CR(AL) *1459*
Sinemet(AL) *1459*
SIPONIMOD 1239
SIROLIMUS 1346
SITAGLIPTIN 92, 93
SITAGLIPTIN + METFORMIN 85, 86
Sitagliptin Lupin (GQ) *93*, *94*
Sitagliptin Mylan(AF) *93*, *94*
Sitagliptin Sandoz Pharma (SZ) *93*, *94*
Sitagliptin SUN(RA) *93*, *94*
SITAGLIPTIN/METFORMIN 50/1000 SUN (RA) *85*, *86*
SITAGLIPTIN/METFORMIN 50/500 SUN (RA) *85*, *86*
SITAGLIPTIN/METFORMIN 50/850 SUN (RA) *86*
Sitagliptin/Metformin Mylan 50/1000(AF) *85*, *86*
Sitagliptin/Metformin Mylan 50/500(AF) *85*, *86*
Sitagliptin/Metformin Mylan 50/850(AF) *86*
Sitagliptin/Metformin Sandoz (SZ) *85*, *86*
Sitagliptin/Metformin Sandoz XR (SZ) *86*, *87*
Sitaglo (CR) *93*, *94*
SKIN EMOLLIENT 1661
Skyrizi(VE) *1092*, *1099*
Slenyto(AS) *1486*
Sno-Pro(SB) *1618*
Sodibic(AS) *255*
SODIUM CHLORIDE 1659

SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE 1700
SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID 62
SODIUM PHENYLBUTYRATE 109
SODIUM POLYSTYRENE SULFONATE 1677
Sodium Valproate Sandoz (SZ) *1437*, *1438*
SOFOSBUVIR + VELPATASVIR 312
SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR 312
Sofradex(SW) *1575*
Soframycin(SW) *1575*
Solaraze 3% Gel(YN) *1663*
Solavert(RF) *131*
Solian 100(SW) *1473*
Solian 200(SW) *1473*
Solian 400 (SW) *1473*
Solian Solution(SW) *1473*
Solone (IL) *264*
SoloSite Gel 36361338(SN) *1695*
Solu-Cortef(PF) *27*, *263*
Solugel 10336(JJ) *1695*
Solu-Medrol (PF) *263*
Solu-Medrol(PF) *264*
Solu-Medrone(LM) *264*
Somac (NQ) *46*, *47*, *48*
Somac(NQ) *46*, *47*, *48*
Sone (IL) *265*
SONIDEGIB 433
SORAFENIB 423, 424
Sorbact Absorption Dressing S98222(BV) *1695*
Sorbact Foam Dressing S98310(BV) *1696*
Sorbact Foam Dressing S98315(BV) *1696*
Sorbact Foam Gentle Border 98532(BV) *1696*
Sorbact Foam Gentle Border 98533(BV) *1696*
Sorbact Gel Dressing S98137(BV) *1695*
Sorbact Ribbon Gauze S98118(BV) *1696*
Sorbact Ribbon Gauze S98120(BV) *1696*
Sorbact Superabsorbent 98501(BV) *1696*
Sorbact Superabsorbent 98503(BV) *1696*
Sorbsan 1410(UM) *1684*
Sorbsan 1411(UM) *1683*
Sotacor(RW) *131*
SOTALOL 131
Sotalol Sandoz (SZ) *131*
Sotyktu(BQ) *1249*
SOY LECITHIN + TOCOPHEROL + VITAMIN A 1574
SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE 1617
Sozol(RW) *46*, *47*, *48*
Span-K(AS) *104*
Spedra(FK) *1665*
Spiolto Respimat(BY) *1533*
Spiractin 100(AF) *147*
Spiractin 25(AF) *147*
Spiriva Respimat(BY) *1536*, *1537*
Spiriva(BY) *1537*
SPIRONOLACTONE 147
Spironolactone Viatris 100(AL) *147*
Spironolactone Viatris 25(AL) *147*
Spren 100(OW) *112*, *1657*
Sprycel(BQ) *325*, *326*, *327*, *328*, *330*, *331*, *333*, *335*
Stalevo 100/25/200mg (SZ) *1460*
Stalevo 125/31.25/200mg (SZ) *1460*
Stalevo 150/37.5/200mg (SZ) *1460*
Stalevo 200/50/200mg (SZ) *1460*
Stalevo 50/12.5/200mg (SZ) *1460*
Stalevo 75/18.75/200mg (SZ) *1460*
Staphylex 250(AF) *279*
Staphylex 500(AF) *279*, *280*
Stelara(JC) *1189*, *1192*, *1193*, *1195*, *1198*, *1201*, *1204*, *1207*, *1211*, *1217*, *1223*, *1230*
Stelax 10 (RW) *1360*
Stelax 25 (RW) *1360*
Stemetil (Ireland)(OJ) *56*, *57*
Stemetil(SW) *28*, *56*, *57*
Steripaste 3610(MH) *1682*
STIRIPENTOL 1453
Stromectol(MK) *1516*
SUCROFERRIC OXYHYDROXIDE 1579
SULFASALAZINE 70
Sulprix (AF) *1473*
Sulprix(AF) *1473*
SULTHIAME 1453
Sumagraine Migraine Relief(GQ) *1428*
Sumatran (OW) *1428*
SUMATRIPTAN 1428
Sumatriptan generichealth(GQ) *1428*
Sumatriptan Sandoz (SZ) *1428*
SUNITINIB 424, 425, 426, 427
Sunitinib MSN (LR) *425*, *426*, *427*, *428*
Sunitinib MSN(LR) *425*, *426*, *427*
Sunitinib Sandoz (SZ) *425*, *426*, *427*
Sunitinib Sandoz(SZ) *425*, *426*, *427*, *428*
SUNSCREENS 1661
Sunsense Comfort SPF 50+(EO) *1661*
Sunsense Sensitive SPF 50+(EO) *1661*
SUPIROCIN (JM) *1662*
Suprasorb G 33631(LC) *1695*
Supriad Cream(XT) *226*, *227*, *228*
Supriad Fatty Ointment(XT) *226*, *227*, *228*
Supriad Ointment(XT) *226*, *227*, *228*
Surepress 650947(CC) *1678*
Surepress 650948(CC) *1678*
Sutent (PF) *425*, *426*, *427*, *428*
Sutent(PF) *425*, *426*, *427*
Symbicort Rapihaler 100/3(AP) *1520*, *1522*, *1523*
Symbicort Rapihaler 200/6(AP) *1522*, *1524*
Symbicort Rapihaler 50/3(AP) *1522*, *1523*
Symbicort Turbuhaler 100/6(AP) *1521*, *1522*
Symbicort Turbuhaler 200/6(AP) *1521*, *1523*, *1524*
Symbicort TURBUHALER 400/12(AP) *1525*
Symmetrel 100 (NV) *1460*
Synacthen Depot 1 mg/1 mL(IX) *257*
Synarel(PF) *260*
Syquet(AF) *1471*, *1472*
Systane (AQ) *1573*, *1574*
Systane(AQ) *1574*
Tacidine (AF) *36*
Tacrograf (RW) *1231*, *1232*
Tacrograf(RW) *1231*, *1232*
TACROLIMUS 1231
Tacrolimus Sandoz (SZ) *1231*, *1232*
Tacrolimus Sandoz(SZ) *1231*, *1232*
Tacrolimus XR Sandoz (SZ) *1231*, *1232*
Tadalaccord (CR) *1666*
TADALAFIL
.Repatriation Pharmaceutical Benefits Scheme 1666
Tadalafil GH (GQ) *1666*
Tadalafil GH(GQ) *1666*
Tadalafil Sandoz (SZ) *1666*
Tadalafil Sandoz(SZ) *1666*
TAFAMIDIS 1512
Tafinlar(NV) *381*, *382*
TAFLUPROST 1551
Tagrisso(AP) *378*, *379*, *380*, *381*
Takhzyro(TK) *129*
Talam (RW) *1488*
Talam(RW) *1488*
Taltz(LY) *1069*, *1072*, *1076*, *1082*, *1089*

Tamate (AF).....*1454*, *1455*, *1456*
Tambocor(IL)..... *131*
Tamosin(OX)..... *456*, *457*
TAMOXIFEN..... 456, 457
Tamoxifen Sandoz (SZ)..... *456*, *457*
Tamsil (RW)..... *220*
Tamsil(RW)..... *1660*
TAMSULOSIN 1668
Tamsulosin Lupin SR (GQ)..... *1668*
Tamsulosin Sandoz SR (SZ)..... *1668*
Tamsulosin Sandoz SR(SZ)..... *1668*
Tanilone (Fatty) (AS)..... *226*, *227*, *228*
TAPE NON WOVEN RETENTION POLYACRYLATE. 1700
TAPE PLASTER ADHESIVE ELASTIC..... 1700
TAPE PLASTER ADHESIVE HYPOALLERGENIC 1701
TAPE PLASTER ADHESIVE WITH SILICONE..... 1701
TAPENTADOL..... 1418
TAR + COAL TAR SOLUTION + SALICYLIC ACID 1663
TAR + TROLAMINE LAURIL SULFATE..... 1661
Targin 10/5mg(MF)..... *1403*, *1632*
Targin 15/7.5mg(MF)..... *1404*, *1632*
Targin 2.5/1.25 mg(MF)..... *1404*, *1632*
Targin 20/10mg(MF)..... *1404*, *1632*
Targin 30/15 mg(MF)..... *1404*, *1632*
Targin 40/20mg(MF)..... *1404*, *1632*
Targin 5/2.5mg(MF)..... *1404*, *1632*
Targin 60/30(MF)..... *1404*, *1632*
Targin 80/40(MF)..... *1404*, *1632*
Tarka 2/180(GO)..... *169*
Tarka 4/240(GO)..... *169*
Tasigna(NV).....*363*, *364*, *365*, *366*, *367*, *368*, *370*
Tazac(RW)..... *36*
Tears Naturale(AQ)..... *1570*
tearsagain(RB)..... *1574*
Tecfidera(BD)..... *1349*, *1350*
TE-DASATINIB (AF).....*325*, *326*, *327*, *328*, *330*, *331*, *333*, *335*
Tegaderm Transparent 1628(MM)..... *1685*
Tegaderm Transparent Island 3582(MM)..... *1685*
Tegaderm Transparent Island 3586(MM)..... *1685*
Teglutik(CS)..... *1512*
Tegretol 100(NV)..... *1434*, *1435*
Tegretol 200(NV)..... *1435*
Tegretol CR 200(NV)..... *1435*
Tegretol CR 400(NV)..... *1435*
Tegretol Liquid(NV)..... *1434*, *1435*
Telfa 8252F(KE)..... *1680*
Telfa 8253F(KE)..... *1680*
Telfa 8254F(KE)..... *1680*
Telfast 120(SW)..... *1676*
Telfast(SW)..... *1676*
TELMISARTAN..... 173
TELMISARTAN + AMLODIPINE..... 182
TELMISARTAN + HYDROCHLOROTHIAZIDE 177, 178
Telmisartan Sandoz(SZ)..... *173*
Telmisartan/HCT Sandoz(SZ)..... *178*
Teltartan (RW)..... *173*
Teltartan HCT 40/12.5 (RW)..... *178*
Teltartan HCT 80/12.5 (RW)..... *178*
Teltartan HCT 80/25 (RW)..... *178*
Temaze (AF).....*1484*, *1485*, *1643*
TEMAZEPAM 1484, 1485, 1643
Temizole 100 (AL)..... *314*
Temizole 140 (AL)..... *314*
Temizole 20 (AL)..... *314*
Temizole 250 (AL)..... *314*
Temizole 5 (AL)..... *314*
Temodal(MK)..... *314*
TEMOZOLOMIDE..... 314
Temozolomide Juno (JX)..... *314*
Temozolomide Juno(JX).....*314*
Temtabs(LN).....*1484*, *1485*, *1643*
Tenaxil SR(RW).....*144*
TenderWet 24 Active 609210(HR).....*1691*
TenderWet 24 Active 609213(HR).....*1691*
TenderWet Active Cavity 609272(HR).....*1691*
TENECTEPLASE 114
TENOFOVIR DISOPROXIL + EMTRICITABINE.....312
Tenofovir Disoproxil Emtricitabine Viatris 300/200(AL)...*313*
Tenofovir EMT GH(GQ).....*313*
Tenofovir/Emtricitabine 300/200 APOTEX (TX) *313*
TENOFOVIR/EMTRICITABINE 300/200 ARX(XT).....*313*
Tenofovir/Emtricitabine Sandoz 301/200(SZ).....*313*
Tenormin(IX).....*149*, *150*
Tensig(RW).....*149*, *150*
Tensocrepe 36300501(BV).....*1680*
Tensocrepe 36301001(BV).....*1680*
Tensocrepe 36307501(BV).....*1680*
Tensopress 71723-00(BV).....*1678*
Tepmetko(SG).....*428*
TEPOTINIB 428
TERBINAFINE
.DERMATOLOGICALS.....219, 220
.Repatriation Pharmaceutical Benefits Scheme.....1660
Terbinafine Sandoz (SZ).....*220*, *1660*
Terbinafine-DRLA(RZ).....*220*
TERBUTALINE
.RESPIRATORY SYSTEM 1519, 1538
TERIFLAGIO(RW).....*1349*
TERIFLUNOMIDE 1348
Teriflunomide Dr.Reddy's (RZ).....*1349*
Teriflunomide GH(GQ) *1349*
Teriflunomide Sandoz (SZ).....*1349*
Terimide(AF) *1349*
TERIPARATIDE
.MUSCULO-SKELETAL SYSTEM.....1373
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS 270
Teriparatide Lupin(GQ)
.MUSCULO-SKELETAL SYSTEM.....*1373*
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS *271*
Terrosa (FX).....*271*, *1373*
Tertroxin(AS).....*268*, *269*
Testavan(IX).....*243*, *244*
Testogel(HB) *243*, *244*
TESTOSTERONE 241, 242, 243
Testosterone ADVZ 1000 (BZ) *245*
TESTOSTERONE UNDECANOATE.....244
TETRABENAZINE.....1513
Tetrabenazine SUN (RA).....*1513*
TETRACOSACTIDE.....257
Tevaripiprazole (TB).....*1473*
Tevaripiprazole(TB).....*1473*
Tevatiapine XR (TB).....*1472*
Tevatiapine XR(TB).....*1471*, *1472*
Teveten Plus 600/12.5(GO).....*175*
Teveten(GO) *170*, *171*
THEOPHYLLINE.....1539
THIAMINE 103, 1655, 1656
Thioprine 50 (AF) *1349*
THIRAZOL (NB) *269*
Thyrogen(GZ).....*257*
THYROTROPIN ALFA 257
Thyrox (IX).....*266*, *267*
TIAGABINE 1436, 1437
TICAGRELOR 113
Tielle MTL101E(KI).....*1691*
Tielle MTL103(KI).....*1691*
TILDRAKIZUMAB.....1139, 1143

TIMOLOL 1549
Timoptol XE(MF) *1549*
Timoptol(MF) *1549*
Tinaderm(BN) *1660*
Tinasil(AF) *220*, *1660*
TIOGUANINE 315
TIOTROPIUM 1536, 1537
TIOTROPIUM + OLODATEROL 1532
TIROFIBAN 113
Tirofiban Juno (JU) *114*
Tixol (AL) *1493*
TNKase (Canada) Medsurge Healthcare Pty Ltd (DZ) .. *114*
TNKase (Canada)(QY) *114*
TOBI podhaler(GO) *292*
Tobi(GO) *291*
Tobra-Day(FF) *291*
TOBRAMYCIN
.ANTIINFECTIVES FOR SYSTEMIC USE. 290, 291, 292
.SENSORY ORGANS 1540, 1541
TOBRAMYCIN SUN (RA) *291*
Tobramycin Viatris(AL) *291*
Tobramycin WKT(JU) *291*
Tobrex(NV) *1541*
TOCILIZUMAB.1150, 1152, 1153, 1154, 1156, 1159, 1161, 1162, 1164, 1165, 1167, 1169, 1173, 1177, 1180, 1183
TOFACITINIB ..1249, 1250, 1252, 1254, 1256, 1259, 1261, 1262, 1264, 1268, 1272, 1277, 1280, 1283, 1287
Tofranil 10(GH) *1487*
Tofranil 25(GH) *1487*
TOLAK 4% ONCE DAILY(AS) *1670*
TOLNAFTATE 1660
TOLVAPTAN 147, 148
Topamax Sprinkle(JC) *1454*, *1455*
TOPIRAMATE 1454, 1455, 1456
Topiramate Sandoz(SZ) *1454*, *1455*, *1456*
Topreloc-XL(CR) *151*, *152*
Toprol-XL 190 (AP) *151*, *152*
Toprol-XL 47.5 (AP) *151*, *152*
Toprol-XL 95 (AP) *151*, *152*
TOREMIFENE 457
Toujeo Solostar(SW) *74*
Trajenta(BY) *91*
Trajentamet(BY) *82*, *83*
TRAMADOL 29, 1420, 1421, 1422
Tramadol AN(JU) *29*, *1420*, *1422*
Tramadol Sandoz (SZ) *29*, *1420*, *1421*, *1422*
Tramadol Sandoz SR (SZ) *1423*, *1424*
Tramadol SR generichealth(GQ) *1423*, *1424*
Tramal 100(CS) *29*, *1420*, *1422*
Tramal SR 100(CS) *1423*
Tramal SR 150(CS) *1424*
Tramal SR 200(CS) *1424*
Tramal SR 50(CS) *1424*
Tramal(CS) *1420*, *1421*, *1422*
Tramedo SR (AL) *1423*, *1424*
Tramedo(AF) *1420*, *1421*, *1422*
TRAMETINIB 389, 390
Tranalpha (AF) *164*
TRANDOLAPRIL 164
TRANDOLAPRIL + VERAPAMIL 169
TRANEXAMIC ACID 125
Tranexamic Acid Lupin (GQ) *126*
Transiderm-Nitro 25(SZ) *132*, *133*
Transiderm-Nitro 50(SZ) *132*, *133*
TRANYLCYPROMINE 1492
TRASTUZUMAB 431, 432
Travatan(NV) *1551*
TRAVOPROST 1551
TRAVOPROST + TIMOLOL 1551, 1552
Trazent (AF) *1349*
Trelegy Ellipta 100/62.5/25(GK) *1531*
Trelegy Ellipta 200/62.5/25(GK) *1531*
Tremfya(JC) *1059*, *1067*
Trexject(LM) *1351*
TRIAMCINOLONE
.DERMATOLOGICALS 222
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS 265
TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN 1575
Triasyn 2.5/2.5(SW) *168*, *169*
Triasyn 5.0/5.0(SW) *168*, *169*
Tricortone(LN) *222*
TRIENTINE 109
Trientine Dr. Reddy's(RZ) *110*
Trientine Waymade (IX) *110*
Trifeme 28(FZ) *240*
TRIFLURIDINE + TIPIRACIL 319, 320
TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER 1618
TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER 1618
TRIGLYCERIDES MEDIUM CHAIN FORMULA 1596
TRIHEXYPHENIDYL (BENZHEXOL) 1457
Trileptal(NV) *1436*
Trimbow(EU) *1530*
TRIMETHOPRIM 287
TRIMETHOPRIM + SULFAMETHOXAZOLE 287, 288
Trimethoprim Viatris(MQ) *287*
Triprim(RW) *287*
TRIPTORELIN 455
Triquilar ED(BN) *240*
Tritace 1.25 mg(SW) *162*, *163*
Tritace 10 mg (SW) *162*, *163*
Tritace 2.5 mg (SW) *162*, *163*
Tritace 5 mg(SW) *162*, *164*
Tritace(SW) *162*, *163*
Trovas (RA) *186*, *187*
Trovas(RA) *187*
Trulicity(LY) *95*
Trusamide(AF) *1548*
Trusopt (MF) *1548*
Trust Aspirin EC 100(CR) *1658*
Trust Cetirizine (CR) *1676*
Trust Coloxease(CR) *1654*
Trust Cystitis Relief(CR) *1667*
Trust Decongestant Nasal Spray (CR) *1676*
Trust Deworm(CR) *1675*
Trust Fem V 3 Day Cream (CR) *1664*
Trust Fem V 6 Day Cream(CR) *1665*
Trust Fexit 120 (CR) *1676*
Trust for Kids Paracetamol 6 to 12 years (CR) *1672*
Trust HydroCortic Cream (CR) *1662*
Trust Loratadine (CR) *1676*
Trust Loratadine Antihistamine(RM) *1676*
Trust Nystatin Oral Drops (CR) *1653*
Trust Sinus & Nasal Decongestant (CR) *1676*
Trust Terbinafine Cream(CR) *1660*
Tryzan Caps 1.25(AF) *162*, *163*
Tryzan Caps 10(AF) *162*, *163*
Tryzan Caps 2.5 (AF) *162*, *163*
Tryzan Caps 5 (AF) *162*, *163*
Tryzan Tabs 1.25 (AF) *162*, *163*
Tryzan Tabs 10 (AF) *162*, *163*
Tryzan Tabs 2.5(AF) *162*, *163*
Tryzan Tabs 5 (AF) *162*, *164*
Tubegauz 0501633(SS) *1681*
Tubifast 2434(MH) *1681*
Tubifast 2436(MH) *1681*
Tubifast 2438(MH) *1681*

Tubigrip 1479(MH) *1681*
Tubigrip 1480(MH) *1681*
Tubigrip 1481(MH) *1681*
Tubigrip 1482(MH) *1681*
Tubigrip 1483(MH) *1681*
Tubigrip 1484(MH) *1681*
Tubigrip 1486(MH) *1681*
Tubigrip B 1520(MH) *1680*
Tubigrip C 1545(MH) *1681*
Tubigrip D 1546(MH) *1680*
Tubigrip E 1547(MH) *1680*
Tubigrip F 1548(MH) *1680*
Twynsta(BY) *182*
Tykerb(NV) *398*, *399*
Tylactin Build 20(QH) *1614*
Tylactin Complete(QH) *1614*
Tylactin RTD(QH) *1614*
TYR Anamix infant(SB) *1609*
TYR Anamix junior LQ(SB) *1604*
TYR Anamix Junior(SB) *1609*
TYR cooler 20(VF) *1609*
TYR Easy Shake & Go(OH) *1604*
TYR Easy Tablet(OH) *1603*
TYR explore5(VF) *1611*
TYR Lophlex LQ 20(SB) *1609*
TYR Lophlex(SB) *1609*
TYR Sphere20(VF) *1613*
Tyrosine 1000(VF) *1618*
TYROSINE WITH CARBOHYDRATE 1618
ultibro breezhaler 110/50(NV) *1532*
UMECLIDINIUM 1537
UMECLIDINIUM + VILANTEROL 1533
UPADACITINIB 1290, 1291, 1293, 1296, 1297, 1300, 1301, 1304, 1306, 1307, 1310, 1315, 1319, 1323, 1326, 1329, 1332
Ural Sachets (AS) *1667*
Uramet (AS) *296*
UREA 1660
Urederm(KY) *1660*
Uremide (AF) *144*, *145*
UREMIDE 20 (AF) *27*, *145*
Urex-Forte(RW) *144*, *145*
UrgoClean Pad 100370(UG) *1691*
UrgoClean Pad 100372(UG) *1691*
UrgoK2 100396(UG) *1678*
UrgoK2 100397(UG) *1678*
UrgoK2 Lite 100400(UG) *1679*
UrgoK2 Lite 100401(UG) *1678*
UrgoStart Border 100480(UG) *1686*
UrgoStart Border 100481(UG) *1686*
UrgoStart Border 100482(UG) *1686*
UrgoStart Contact-Interface-Tul 100380(UG) *1684*
UrgoStart Contact-Interface-Tul 100381(UG) *1685*
UrgoStart Pad 100376(UG) *1686*
UrgoStart Pad 100377(UG) *1686*
UrgoStart Pad 100378(UG) *1686*
UrgoStart Plus Border 100460(UG) *1698*
UrgoStart Plus Border 100461(UG) *1699*
UrgoStart Plus Border 100462(UG) *1699*
UrgoStart Plus Non Adhesive 100441(UG) *1699*
UrgoStart Plus Non Adhesive 100442(UG) *1699*
UrgoStart Plus Pad 100421(UG) *1699*
UrgoStart Plus Pad 100422(UG) *1699*
UrgoTul Absorb Silicone Border 102203(UG) *1686*
UrgoTul Contact 100351(UG) *1684*
UrgoTul Lite Border 100357(UG) *1696*
UrgoTul Lite Border 10035710(UG) *1697*
Uro-Carb(YN) *1508*
Uromitexan(BX) *1580*
Urorec(YN) *1667*, *1668*
URSODEOXYCHOLIC ACID 58
Ursodox GH (GQ) *58*
Ursofalk(FD) *58*
Ursosan (BZ) *58*
USTEKINUMAB 1187, 1189, 1192, 1193, 1195, 1198, 1201, 1204, 1207, 1211, 1217, 1223
Utrogestan(HB) *248*
Vabysmo(RO) *1559*, *1560*
Vaclovir (AF) *308*
Vaclovir(AF) *308*
Vagifem Low (NO) *245*, *246*
VALACICLOVIR 307, 308
Valaciclovir APOTEX (GX) *308*
Valaciclovir APOTEX(GX) *308*
Valaciclovir generichealth (GQ) *308*
Valaciclovir generichealth(GQ) *308*
Valaciclovir RBX (RA) *308*
Valaciclovir RBX(RA) *308*
Valaciclovir Sandoz (SZ) *308*
Valaciclovir Sandoz(SZ) *308*
Valaciclovir SZ (HX) *308*
Valacor 500(CR) *308*
Valine 1000(VF) *1618*
Valine 50(VF) *1618*
VALINE WITH CARBOHYDRATE 1618
Valium(IX) *1482*, *1483*, *1643*
Valpam 2(RW) *1482*, *1483*, *1643*
Valpam 5(RW) *1482*, *1483*, *1643*
Valprease 200(RW) *1437*, *1438*
Valprease 500(RW) *1437*, *1438*
Valpro EC 200(AF) *1437*, *1438*
Valpro EC 500(AF) *1437*, *1438*
VALPROATE 1437
Valproate Winthrop EC 200 (WA) *1437*, *1438*
Valproate Winthrop EC 500 (WA) *1437*, *1438*
VALSARTAN 173, 174
VALSARTAN + HYDROCHLOROTHIAZIDE 178, 179
Valtrex(RW) *308*
Vancocin(AS) *62*
VANCOMYCIN
.ALIMENTARY TRACT AND METABOLISM 62
.ANTIINFECTIVES FOR SYSTEMIC USE 294, 295
Vancomycin Alphapharm(AF) *294*, *295*
Vancomycin BNM 125mg (BZ) *62*
Vancomycin BNM 250mg (BZ) *62*
VARENAPIX(TX) *1510*, *1511*
VARENICLINE 1509, 1510
Varenicline Viatris (AF) *1510*
Vasafil 100 (RW) *1666*
Vasafil 25(RW) *1666*
Vasafil 50 (RW) *1666*
Vasocardol CD (AV) *157*
Vasocardol(AV) *158*
Vedafil (AF) *1666*
Vedafil(AF) *1666*
Vedilol 12.5 (RW) *153*, *154*
Vedilol 25 (RW) *154*
Vedilol 3.125(RW) *154*
Vedilol 6.25 (RW) *154*
VEDOLIZUMAB 1337, 1338, 1340, 1341, 1342, 1343
Velabine (XT) *321*
Velmetia(XT) *85*, *86*
Velphoro(VL) *1579*, *1580*
Veltassa(CS) *1578*
VEMURAFENIB 383, 384
Venclexta(VE) *448*, *449*, *450*, *451*
VENETOCLAX 448, 449, 450
VENLAFAXINE 1494
Venlafaxine generichealth XR (GQ) *1494*, *1495*
Venofer(VL) *127*

Ventolin CFC-Free with dose counter(GK) *29*, *1518*
Ventolin Nebules(GK) *29*, *1518*
Ventolin(GK) *1538*
Vepesid(LM) *321*
VERAPAMIL 157
VERICIGUAT 134, 135
Verquvo(BN) *135*, *136*
Verzenio(LY) *390*, *391*
VesiCulture(LM) *467*
Vexazone(AF) *88*, *89*
Vfend(PF) *300*, *301*
Viagra (UJ) *1666*
Viagra(UJ) *1666*
VIGABATRIN 1438
VILDAGLIPTIN 94
VILDAGLIPTIN + METFORMIN 87
Vimcosa (CR) *1442*, *1443*, *1444*, *1445*
Vimcosa(CR) *1442*, *1443*, *1446*, *1447*
Vimpat (UC) *1442*, *1443*, *1446*, *1447*
Vimpat(UC) *1442*, *1443*, *1444*, *1445*
VINORELBINE 320
ViruPOS(AE) *1541*
Viscopaste 4948(SN) *1682*
Viscotears Gel PF(UO) *1567*
Viscotears(UO) *1566*, *1567*
VISMODEGIB 435
Vita-B12 (GH) *127*
Vita-B12(GH) *1658*
VITAMINS, MINERALS AND TRACE ELEMENTS 1618
VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE 1619
Vitrakvi(BN) *412*, *414*
VITRAKVI(BN) *412*, *414*
Vizo-PF Dorzolatim (AE) *1549*
Vliwasorb Pro 32641(LC) *1698*
Vliwasorb Pro 32643(LC) *1698*
Vliwasorb Pro 32644(LC) *1698*
Volirop 12.5(ZS) *153*, *154*
Volirop 25(ZS) *154*
Volirop 3.125 (ZS) *154*
Volirop 6.25(ZS) *154*
Voltaren 100(NV) *1353*
Voltaren 25(NV) *1354*
Voltaren 50(NV) *1354*
Voluven 6%(PK) *128*
VORICONAZOLE 299, 300
Voriconazole Sandoz(SZ) *300*
VORINOSTAT 432, 433
Vosevi(GI) *312*
VOSORITIDE 1374
Votrient(NV) *420*, *421*, *422*
Voxzogo(IO) *1374*
Vttack (AF) *300*
Vumerity(BD) *1350*
Vyepti(LU) *1429*
Vyndamax(PF) *1513*
Vytorin (AL) *215*, *216*, *217*, *218*
Vyvanse(TK) *1498*
Vzole(RW) *300*
Wagner Health Paracetamol(BG) *1424*, *1425*, *1673*
WARFARIN 110
Waxsol(GO) *1677*
Wellvone(AS) *1514*
WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE 1619
WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE 1619
WOOL ALCOHOLS 1660
WP Carbimazole(TN) *269*
Xadago(CS) *1465*
Xalacom (AS) *1551*
Xalamol 50/5(AF) *1551*
Xalaprost(AF) *1550*, *1551*
Xalatan (AS) *1550*, *1551*
Xalkori(PF) *386*, *387*
Xarelto(BN) *121*, *122*, *123*, *124*, *125*
Xatral SR(SW) *1667*
Xelabine (AL) *317*
Xelevia(XT) *93*, *94*
Xeljanz(PF) *1250*, *1252*, *1254*, *1256*, *1259*, *1261*, *1262*, *1264*, *1268*, *1272*, *1277*, *1280*, *1283*, *1287*, *1290*
Xenical(PB) *1655*
Xergic(AF) *1676*
Xgeva(AN) *1371*
Xifaxan(NE) *62*
Xigduo XR 10/1000(AP) *78*, *79*
Xigduo XR 10/500(AP) *78*, *79*
Xigduo XR 5/1000(AP) *78*, *79*
XLYS, LOW TRY Maxamum(SB) *1607*
XOROX (IX) *1541*
Xospata(LL) *411*, *412*
XP Maxamum(SB) *1608*
Xtandi(LL) *460*, *461*
Xylocaine Viscous(AS) *1661*
Xylocard 500(AS) *130*
YELLOW JACKET VENOM 1576
Yonsa Mpred(RA)
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS *465*
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS *261*
Yuflyma (EW) *490*, *492*, *494*, *495*, *500*, *504*, *506*, *508*, *509*, *511*, *512*, *520*, *522*, *525*, *527*, *537*, *539*, *549*, *551*, *660*, *668*, *681*, *684*
Yuflyma(EW) . *481*, *482*, *487*, *489*, *498*, *502*, *516*, *535*, *540*, *544*, *547*, *553*, *564*, *567*, *573*, *576*, *579*, *582*, *585*, *588*, *590*, *593*, *603*, *606*, *616*, *621*, *626*, *632*, *636*, *641*, *651*, *656*, *699*, *716*, *720*, *724*, *729*, *734*, *738*, *780*, *781*, *786*, *799*, *806*
Z.S.C.(RW) *1664*
Zabep(AL) *48*, *49*, *50*
Zactin Tablet(AF) *1490*
Zactin(AF) *1490*
Zan-Extra 10/10(GO) *167*
Zan-Extra 10/20(GO) *167*
Zanidip(GO) *156*
ZANUBRUTINIB 406, 407
Zarontin(IX) *1433*
Zatamil (EO) *229*, *230*, *231*
Zatamil(EO) *229*, *230*
Zedd 500(RW) *1669*
Zejula(GK) *437*, *438*, *439*, *440*, *441*, *442*, *443*, *444*
Zeklen 10/10 mg(AF) *216*, *217*
Zeklen 10/20 mg(AF) *216*, *217*
Zeklen 10/40 mg(AF) *215*, *218*
Zeklen 10/80 mg(AF) *215*, *217*
Zelboraf(RO) *384*
Zeldox(UJ) *1467*
Zelitrex (RF) *308*
Zelitrex(RF) *308*
Zempreon CFC-Free with dose counter(AL) *29*, *1518*
Zentel(AS) *1515*
Zeposia(CJ) *1234*, *1236*, *1239*
Zestril(IX) *159*
ZETIN (RW) *221*

Zetuvit Plus 413710(HR) *1698*
Zetuvit Plus 413711(HR) *1698*
Zetuvit Plus 413715(HR) *1698*
Zient 10mg (AF) *201*, *202*
Zimstat (AF) *190*, *191*
Zimstat(AF) *190*, *191*
Zimybe 10/10 (MQ) *216*, *217*
Zimybe 10/20 (MQ) *216*, *217*
Zimybe 10/40 (MQ) *215*, *218*
Zimybe 10/80 (MQ) *215*, *217*
ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN 1664
ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE 1659
Zinnat (UK)(RQ) *285*
Zinnat(AS) *285*
Zinopril 10 (AL) *159*
Zinopril 20(AL) *159*
Zinopril 5 (AL) *159*
ZIPRASIDONE 1467
Ziprasidone GH (GQ) *1467*
ZIPROX(RW) *1467*
ZipZoc 66000747(SN) *1682*
Zircol 10(AL) *156*
Zircol 20(AL) *156*
ZITHRO (RF)
.Repatriation Pharmaceutical Benefits Scheme *1669*
ZITHRO(RW)
.ANTIINFECTIVES FOR SYSTEMIC USE *288*
.SENSORY ORGANS *1540*
Zithromax (PF)
.ANTIINFECTIVES FOR SYSTEMIC USE *288*
.SENSORY ORGANS *1540*
Zithromax(PF)
.Repatriation Pharmaceutical Benefits Scheme *1669*
Zithromax(PF)
.ANTIINFECTIVES FOR SYSTEMIC USE *288*
.SENSORY ORGANS *1540*
Zocor (MQ) *190*, *191*
Zofran syrup 50 mL(AS) *52*, *53*
Zofran Zydis(AS) *54*
Zofran(AS) *53*
ZolaCos CP 10.8/50(28)(AP) *453*
ZolaCos CP 10.8/50(84)(AP) *453*
ZolaCos CP 3.6/50(AP) *453*
Zoladex 10.8 Implant(AP) *452*
Zoladex Implant(AP) *452*
Zoledasta(TX) *1366*
Zoledronate-RDY 5 (RI) *1366*
ZOLEDRONIC ACID 1366
Zoledronic Acid SUN(RA) *1366*
Zolinza(MK) *432*, *433*
ZOLMITRIPTAN 1428
Zoloft(UJ) *1491*
Zoltrip (RW) *1428*
Zomig(AP) *1428*
Zonegran(GH) *1457*
ZONISAMIDE 1457
ZOPICLONE 1674
Zopiclone GH(GQ) *1675*
Zopral (AF) *41*, *42*, *43*
Zopral ODT(AF) *41*, *42*, *43*
Zopral(AF) *41*
Zoton FasTabs(PF) *41*, *42*, *43*
Zotren 4 (RF) *53*
Zotren 8 (RF) *53*
Zotren ODT (RF) *53*, *54*
Zotren ODT(RF) *53*, *54*
ZUCLOPENTHIXOL DECANOATE 1468
Zumenon(GO) *245*, *246*
Zyban(AS) *1508*, *1509*
Zydelig(GI) *408*, *409*
Zydol (RW) *1420*, *1421*, *1422*
Zydol SR 100(RW) *1423*
Zydol SR 150(RW) *1424*
Zydol SR 200(RW) *1424*
Zykadia(NV) *386*
Zyloprim(RW) *1360*, *1361*
Zypine (AF) *1469*
Zypine ODT (AF) *1469*, *1470*
Zypine ODT(AF) *1470*
Zypine(AF) *1469*
Zyprexa Relprevv(PB) *1471*
Zyprexa Zydis(PB) *1469*, *1470*
Zyprexa(PB) *1469*
Zytiga(JC) *464*